DECLARATION OF CONFORMITY
PERMANENT MAKE-UP COLOR

TRADE NAME	BIOTEK
PRODUCT NAME	MOSCOW
PRODUCT CODE	E15S-02 15ml
DESCRIPTION	Mixture for use in tattoos or permanent make-up
PRODUCT USE	Professional use
MANUFACTURER	BIOTEK srl Milano Via R. Farneti 8 Italy P.I. IT10911780152
CONTACT	Tel +39.02.7380144 e-mail security@biotek.it
CONTENT	15ml / 0.5 fl.oz (nominal content)

HEREWITH DECLARE THAT

The product is original, designed and manufactured in Italy by BIOTEK laboratories - ISO 7 cleanroom.

The following Declaration of Conformity is issued by BIOTEK srl under sole responsibility as manufacturer of colors for permanent make-up. This product is intended for professional use only and may only be used by those with the appropriate qualifications that meet the necessary legal requirements established by each country.

The product is designed to perform PMU procedures, permanent make-up, semi-permanent make-up, dermopigmentation, micropigmentation, microblading, corrective aesthetic make-up, epidermal design and scalp pigmentation using adequate electrical or manual equipment suitable for the purpose.

BIOTEK adopts all possible precautions in the design, processing and packaging in order to guarantee a quality product. For this purpose, it has been adopted the ISO9001 Quality System and it has been a certified company since 2007 in the field of design and production processes whose mission is to guarantee customers safe and effective products.

Quality has always been the center of BIOTEK production policy and, following the entry into force of the Regulation (EU) 2020/2081 - which amends Annex XVII of Regulation (EC) no. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) with regard to substances contained in inks for tattoos or permanent make-up - BIOTEK has implemented an internal protocol to validate the safety levels related to the raw materials used in the BIOTEK colors line production phases as follows:

Safety rating levels:

I LEVEL - RESEARCH OF AUTHORIZED AND/OR ALLOWED RAW MATERIALS
II LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRELIMINARY PRODUCTION PHASE
III LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRODUCTION PHASE
IV LEVEL - CLINICAL AND TOXICOLOGICAL TESTS
V LEVEL - STERILIZATION ISO 11137 / VDmax 25 Method
VI LEVEL - STABILITY TESTS OF FINAL PRODUCT
VII LEVEL - TRACEABILITY OF THE FINAL PRODUCT

BIOTEK declares compliance with current European and non-European regulations where the product has been placed on the market. In particular, it responds to the indications expressed in the (EU) Regulation of the European Commission of 14.12.2020 and in the amendments to Annex XVII of Regulation (EC) No. 1907/2006.

Substances falling within one or more of the following points:

(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:
- carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation
- reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation
- skin sensitiser category 1, 1A or 1B
- skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2
- serious eye damage category 1 or eye irritant category 2

(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*)

(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex

(d) substances listed in Appendix 13 to this Annex.

List of substances with specific concentration limits:

TABLE OF HEAVY METAL VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Mercury	231-106-7	7439-97-6	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Nickel	231-111-4	7440-02-0	0,0005 %	5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Organometallic tin	231-141-8	7440-31-5	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Antimony	231-146-5	7440-36-0	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Arsenic	231-148-6	7440-38-2	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Barium **	231-149-1	7440-39-3	0,05 %	500	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Cadmium	231-152-8	7440-43-9	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Chromium‡	231-157-5	7440-47-3	0,00005 %	0,5	0,02	UNI EN 71-3:2019	✓ COMPLIANT
Cobalt	231-158-0	7440-48-4	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Copper **	231-159-6	7440-50-8	0,025 %	250	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Zinc **	231-175-3	7440-66-6	0,2 %	2.000	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Lead	231-100-4	7439-92-1	0,00007 %	0,7	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Selenium	231-957-4	7782-49-2	0,0002 %	2	0,3	UNI EN 71-3:2019	✓ COMPLIANT
** Soluble Cromo‡ VI							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of heavy metals.

However, general precautions are recommended to ensure public safety.
Pigments must not be applied in case of allergy or intolerance to any of the ingredients shown on the label. The color may contain traces of Nickel and/or Chromium: it can cause allergic reactions. A sensitivity test should always be done before treatment. A positive reaction to the test requires a medical examination. Biotek assumes no responsibility for particular allergic reactions due to individual sensitivity towards colors.

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TABLE OF POLYCYCLIC-AROMATIC HYDROCARBONS VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % concentrazioni singole	0,5	0,2	AfPS GS 2014:01 PAK	✓ **COMPLIANT**
Benzo(a)pyrene	200-028-5	50-32-8	0,0000005%	0,005	0,0025	AfPS GS 2014:01 PAK	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Polycyclic-aromatic Hydrocarbons.

TABLE OF AROMATIC AMINES VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Methanol	200-659-6	67-56-1	11 %	110.000	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-anisidine **	201-963-1	90-04-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-toluidine **	202-429-0	95-53-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methyl-m- phenylenediamine **	202-453-1	95-80-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloroaniline **	203-401-0	106-47-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-thiodianiline **	205-370-9	139-65-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-naphthylamine**	202-080-4	91-59-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Aniline **	200-539-3	62-53-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Benzidine **	202-199-1	92-87-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-toluidine **	203-403-1	106-49-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-o-tolilazo-o-toluidine **	202-591-2	97-56-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methoxy-m- phenylenediamine **	210-406-1	615-05-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'- methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-amino-3-f luorophenol **	402-230-0	399-95-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,6-xylidine	201-758-7	87-62-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4-xylidine	202-440-0	95-68-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Aromatic Amines.

BIOTEK MILANO

TABLE OF ALLERGENIC AND CARCINOGENIC DYES VALUE

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Pigment Red 7 (PR7) CI 12420	229-315-3	6471-51-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 9 (PR9) CI 12460	229-104-6	6410-38-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 15 (PR15) CI 12465	229-105-1	6410-39-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 210 (PR210) CI 12477	612-766-9	61932-63-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 74 (PO74)		85776-14-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 65 (PY65) CI 11740	229-419-9	6528-34-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 74 (PY74) CI 11741	228-768-4	6358-31-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 12 (PR12) CI 12385	229-102-5	6410-32-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 14 (PR14) CI 12380	229-314-8	6471-50-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 17 (PR17) CI 12390	229-681-4	6655-84-1	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 112 (PR112) CI 12370	229-440-3	6535-46-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 14 (PY14) CI 21095	226-789-3	5468-75-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 55 (PY55) CI 21096	226-789-3	6358-37-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 2 (PR2) CI 12310	227-930-1	6041-94-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 22 (PR22) CI 12315	229-245-3	6448-95-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 146 (PR146) CI 12485	226-103-2	5280-68-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 269 (PR269) CI 12466	268-028-8	67990-05-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange16 (PO16) CI 21160	229-388-1	6505-28-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 1 (PY1) CI 11680	219-730-8	2512-29-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 12 (PY12) CI 21090	228-787-8	6358-85-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 87 (PY87) CI 21107:1	239-160-3	5110-84-6 14110-84-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 97 (PY97) CI 11767	235-427-3	12225-18-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 13 (PO13) CI 21110	222-530-3	3520-72-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 34 (PO34) CI 21115	239-898-6	15793-73-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 83 (PY83) CI 21108	226-939-8	5567-15-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 1 (SR1) CI 12150	214-968-9	1229-55-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Orange 24 (AO24) CI 20170	215-296-9	1320-07-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 23 (SR23) CI 26100	201-638-4	85-86-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 73 (AR73) CI 27290	226-502-1	5413-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 3 CI 11855	220-600-8	2832-40-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Green 16	603-214-8	12768-78-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 26	223-178-3	3761-53-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Violet 17	223-942-6	4129-84-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Basic Red 1	213-584-9	989-38-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 106	602-285-2	12223-01-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 124	612-788-9	61951-51-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 35	602-260-6	12222-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Orange 37	602-312-8	12223-33-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 1	220-704-3	2872-52-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 17	221-665-5	3179-89-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 9	228-919-4	6373-73-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 3	603-635-7	1325-82-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 39	264-654-0	64070-98-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Yellow 2	200-455-7	60-11-7	0,1 %»	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
** Solubile ‡Cromo VI.							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Allergenic and Carcinogenic Dyes.

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LABORATORIES

BIOTEK avails itself of the support of several authoritative analysis laboratories for the verification of colors compliance:

- *BUZZI* (Prato) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 052 L
- *EUROLAB* (Vicenza) Italy Accredited Analysis Laboratory ACCREDIA /LAB N° 0856L
- *CTL GmbH* (Bielefeld) Germany - International Laboratory specialized in tattoo and pmu color analysis
- *COMPLIFE* (Pavia) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 1318L - for toxicological analysis
- *EUROFINS BIOLAB (Milano)* Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 0085L - for Stability test and Validation of sterilization process Vdmax25

BIOTEK also makes use of other laboratories and authoritative research institutions such as:

- *University of Milan*
- *University of Studies of Pavia*

ANALYSIS METHODS

The laboratories selected by BIOTEK adopt different methods of analysis, applying the most suitable one in relation to the research to be carried out. In particular:

ANALISYS	METHODS
Determination of Aromatic Amines from Azo Dyes	UNI EN ISO 17234-1:2015 *(Leather)*
Determination of Polycyclic-Aromatic Hydrocarbons (PAH)	AfPS GS 2014:01
Determination of Heavy Metals	UNI EN 71-3:2019 (*Artificial Sweat Extraction)*
Determination of Allergenic and Carcinogenic Dyes	UNI EN 16373-2:2014 *(Textile)*

TOXICOLOGICAL INFORMATION

Extensive clinical tests are performed to support product quality and safety.
Cytotoxicity - Phototoxicity - Skin irritation - Intracutaneous reactivity

Toxicological data declare that the ingredients used for the production there are no related risk effects at concentrations under foreseeable conditions according to the indicated use.

INGREDIENTS

The ingredients are expressed on the label affixed to the bottle. The ingredients and wordings may vary depending on the regulations required by the country of destination.

DURATION

The BIOTEK color subjected to the *Accelerated Stability Study* and *Sterility Test ISO 11737-2:2009* maintains unchanged the qualitative and sterility parameters.
The shelf life of a closed packaged product can be determined in 5 years, when stored intact from 5°C to 40°C
See the date indicated on the label or package.
P.A.O. (Period After Opening): 12 months when stored from 5°C to 40°C.

STERILITY

The packaged product is treated by Gammatom - a company specialized in sterilization treatments - with an irradiation dose of 25 kGy. The dose is identified following the validation of the sterilization process carried out by the Eurofins Laboratory according to the VdMax25 method required by the standard UNI EN ISO 11137-2.

TRACEABILITY

The color bottle is marked by an identifying batch (Lot Number) that allows complete traceability of the product, of the pigments used during the production phase and of the sterilization phase.

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PACKAGING

BIOTEK color is packaged in an airless container. This technology makes possible to optimally preserve the content as it does not come into contact with the air, it does not undergo variations and preserves its properties and sterility. An airless bottle has many advantages: greater safety thanks to the non-return valve and the double-chamber bottom; it reduces the use of preservatives in the product; it guarantees greater hygiene, in addition to the calibrated use of the product.

CORRECT USE OF THE PRODUCT

Directions for correct use:

- Shake well before use
- Do not use after the expiration date indicated on the bottle
- Do not pollute the content of the bottle
- Do not mix color
- The use must be in accordance with the intended purpose
- Do not mix the product with colors of other brands
- Keep out of reach of children
- Do not ingest and do not inhale
- Avoid contact with eyes
- Do not pour the used color back into the original bottle
- Do not use unlabeled bottles
- Do not use the product contained in a broken or defective bottle
- Store the product in a dry place at room temperature
- Keep away from heat sources
- Store in a dark environment
- Avoid freezing of the product
- Pour the color only in sterile capsules
- Do not use the sterile contents of the capsules on multiple patients
- Respect the operational hygiene protocol and the hygiene regulations of each country

Material Safety Data Sheet (MSDS) is provided for each reference of the BIOTEK line. The technical document takes into consideration the chemical substances and their mixtures regarding the physico-chemical, toxicological and environmental risk information, necessary for correct and safe handling of the mixtures.

What is declared in this Certificate of Conformity is a synthetic extract of the complete General BIOTEK Color Dossier *(Component Control File MO 70.02, Analysis Report, Project and Production File drawn up according to ISO 9001:2015)* available only to the Health Authorities upon specific request.



Milan, 01.01.2021

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DECLARATION OF CONFORMITY
PERMANENT MAKE-UP COLOR

TRADE NAME	BIOTEK
PRODUCT NAME	IBIZA
PRODUCT CODE	E15S-05 15ml
DESCRIPTION	Mixture for use in tattoos or permanent make-up
PRODUCT USE	Professional use
MANUFACTURER	BIOTEK srl Milano Via R. Farneti 8 Italy P.I. IT10911780152
CONTACT	Tel +39.02.7380144 e-mail security@biotek.it
CONTENT	15ml / 0.5 fl.oz (nominal content)

HEREWITH DECLARE THAT

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The product is designed to perform PMU procedures, permanent make-up, semi-permanent make-up, dermopigmentation, micropigmentation, microblading, corrective aesthetic make-up, epidermal design and scalp pigmentation using adequate electrical or manual equipment suitable for the purpose.

BIOTEK adopts all possible precautions in the design, processing and packaging in order to guarantee a quality product. For this purpose, it has been adopted the ISO9001 Quality System and it has been a certified company since 2007 in the field of design and production processes whose mission is to guarantee customers safe and effective products.

Quality has always been the center of BIOTEK production policy and, following the entry into force of the Regulation (EU) 2020/2081 - which amends Annex XVII of Regulation (EC) no. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) with regard to substances contained in inks for tattoos or permanent make-up - BIOTEK has implemented an internal protocol to validate the safety levels related to the raw materials used in the BIOTEK colors line production phases as follows:

Safety rating levels:

I LEVEL - RESEARCH OF AUTHORIZED AND/OR ALLOWED RAW MATERIALS
II LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRELIMINARY PRODUCTION PHASE
III LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRODUCTION PHASE
IV LEVEL - CLINICAL AND TOXICOLOGICAL TESTS
V LEVEL - STERILIZATION ISO 11137 / VDmax 25 Method
VI LEVEL - STABILITY TESTS OF FINAL PRODUCT
VII LEVEL - TRACEABILITY OF THE FINAL PRODUCT

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BIOTEK declares compliance with current European and non-European regulations where the product has been placed on the market. In particular, it responds to the indications expressed in the (EU) Regulation of the European Commission of 14.12.2020 and in the amendments to Annex XVII of Regulation (EC) No. 1907/2006.

Substances falling within one or more of the following points:

(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:
- carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation
- reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation
- skin sensitiser category 1, 1A or 1B
- skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2
- serious eye damage category 1 or eye irritant category 2

(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*)

(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex

(d) substances listed in Appendix 13 to this Annex.

List of substances with specific concentration limits:

TABLE OF HEAVY METAL VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Mercury	231-106-7	7439-97-6	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Nickel	231-111-4	7440-02-0	0,0005 %	5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Organometallic tin	231-141-8	7440-31-5	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Antimony	231-146-5	7440-36-0	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Arsenic	231-148-6	7440-38-2	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Barium **	231-149-1	7440-39-3	0,05 %	500	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Cadmium	231-152-8	7440-43-9	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Chromium‡	231-157-5	7440-47-3	0,00005 %	0,5	0,02	UNI EN 71-3:2019	✓ COMPLIANT
Cobalt	231-158-0	7440-48-4	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Copper **	231-159-6	7440-50-8	0,025 %	250	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Zinc **	231-175-3	7440-66-6	0,2 %	2.000	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Lead	231-100-4	7439-92-1	0,00007 %	0,7	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Selenium	231-957-4	7782-49-2	0,0002 %	2	0,3	UNI EN 71-3:2019	✓ COMPLIANT
** Soluble Cromo‡ VI							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of heavy metals.

However, general precautions are recommended to ensure public safety.
Pigments must not be applied in case of allergy or intolerance to any of the ingredients shown on the label. The color may contain traces of Nickel and/or Chromium: it can cause allergic reactions. A sensitivity test should always be done before treatment. A positive reaction to the test requires a medical examination. Biotek assumes no responsibility for particular allergic reactions due to individual sensitivity towards colors.

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TABLE OF POLYCYCLIC-AROMATIC HYDROCARBONS VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % concentrazioni singole	0,5	0,2	AfPS GS 2014:01 PAK	✓ **COMPLIANT**
Benzo(a)pyrene	200-028-5	50-32-8	0,0000005%	0,005	0,0025	AfPS GS 2014:01 PAK	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Polycyclic-aromatic Hydrocarbons.

TABLE OF AROMATIC AMINES VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Methanol	200-659-6	67-56-1	11 %	110.000	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-anisidine **	201-963-1	90-04-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-toluidine **	202-429-0	95-53-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methyl-m- phenylenediamine **	202-453-1	95-80-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloroaniline **	203-401-0	106-47-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-thiodianiline **	205-370-9	139-65-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-naphthylamine**	202-080-4	91-59-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Aniline **	200-539-3	62-53-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Benzidine **	202-199-1	92-87-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-toluidine **	203-403-1	106-49-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-o-tolilazo-o-toluidine **	202-591-2	97-56-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methoxy-m- phenylenediamine **	210-406-1	615-05-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'- methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-amino-3-f luorophenol **	402-230-0	399-95-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,6-xylidine	201-758-7	87-62-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4-xylidine	202-440-0	95-68-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Aromatic Amines.

BIOTEK MILANO

TABLE OF ALLERGENIC AND CARCINOGENIC DYES VALUE

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Pigment Red 7 (PR7) CI 12420	229-315-3	6471-51-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 9 (PR9) CI 12460	229-104-6	6410-38-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 15 (PR15) CI 12465	229-105-1	6410-39-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 210 (PR210) CI 12477	612-766-9	61932-63-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 74 (PO74)		85776-14-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 65 (PY65) CI 11740	229-419-9	6528-34-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 74 (PY74) CI 11741	228-768-4	6358-31-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 12 (PR12) CI 12385	229-102-5	6410-32-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 14 (PR14) CI 12380	229-314-8	6471-50-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 17 (PR17) CI 12390	229-681-4	6655-84-1	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 112 (PR112) CI 12370	229-440-3	6535-46-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 14 (PY14) CI 21095	226-789-3	5468-75-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 55 (PY55) CI 21096	226-789-3	6358-37-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 2 (PR2) CI 12310	227-930-1	6041-94-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 22 (PR22) CI 12315	229-245-3	6448-95-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 146 (PR146) CI 12485	226-103-2	5280-68-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 269 (PR269) CI 12466	268-028-8	67990-05-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange16 (PO16) CI 21160	229-388-1	6505-28-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 1 (PY1) CI 11680	219-730-8	2512-29-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 12 (PY12) CI 21090	228-787-8	6358-85-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 87 (PY87) CI 21107:1	239-160-3	5110-84-6 14110-84-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 97 (PY97) CI 11767	235-427-3	12225-18-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 13 (PO13) CI 21110	222-530-3	3520-72-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 34 (PO34) CI 21115	239-898-6	15793-73-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 83 (PY83) CI 21108	226-939-8	5567-15-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 1 (SR1) CI 12150	214-968-9	1229-55-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Orange 24 (AO24) CI 20170	215-296-9	1320-07-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 23 (SR23) CI 26100	201-638-4	85-86-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 73 (AR73) CI 27290	226-502-1	5413-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 3 CI 11855	220-600-8	2832-40-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Green 16	603-214-8	12768-78-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 26	223-178-3	3761-53-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Violet 17	223-942-6	4129-84-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Basic Red 1	213-584-9	989-38-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 106	602-285-2	12223-01-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 124	612-788-9	61951-51-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 35	602-260-6	12222-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Orange 37	602-312-8	12223-33-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 1	220-704-3	2872-52-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 17	221-665-5	3179-89-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 9	228-919-4	6373-73-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 3	603-635-7	1325-82-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 39	264-654-0	64070-98-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Yellow 2	200-455-7	60-11-7	0,1 %»	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
** Solubile ‡Cromo VI.							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Allergenic and Carcinogenic Dyes.

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LABORATORIES

BIOTEK avails itself of the support of several authoritative analysis laboratories for the verification of colors compliance:

- *BUZZI* (Prato) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 052 L
- *EUROLAB* (Vicenza) Italy Accredited Analysis Laboratory ACCREDIA /LAB N° 0856L
- *CTL GmbH* (Bielefeld) Germany - International Laboratory specialized in tattoo and pmu color analysis
- *COMPLIFE* (Pavia) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 1318L - for toxicological analysis
- *EUROFINS BIOLAB (Milano)* Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 0085L - for Stability test and Validation of sterilization process Vdmax25

BIOTEK also makes use of other laboratories and authoritative research institutions such as:

- *University of Milan*
- *University of Studies of Pavia*

ANALYSIS METHODS

The laboratories selected by BIOTEK adopt different methods of analysis, applying the most suitable one in relation to the research to be carried out. In particular:

ANALISYS	METHODS
Determination of Aromatic Amines from Azo Dyes	UNI EN ISO 17234-1:2015 *(Leather)*
Determination of Polycyclic-Aromatic Hydrocarbons (PAH)	AfPS GS 2014:01
Determination of Heavy Metals	UNI EN 71-3:2019 (*Artificial Sweat Extraction)*
Determination of Allergenic and Carcinogenic Dyes	UNI EN 16373-2:2014 *(Textile)*

TOXICOLOGICAL INFORMATION

Extensive clinical tests are performed to support product quality and safety.
Cytotoxicity - Phototoxicity - Skin irritation - Intracutaneous reactivity

Toxicological data declare that the ingredients used for the production there are no related risk effects at concentrations under foreseeable conditions according to the indicated use.

INGREDIENTS

The ingredients are expressed on the label affixed to the bottle. The ingredients and wordings may vary depending on the regulations required by the country of destination.

DURATION

The BIOTEK color subjected to the *Accelerated Stability Study* and *Sterility Test ISO 11737-2:2009* maintains unchanged the qualitative and sterility parameters.
The shelf life of a closed packaged product can be determined in 5 years, when stored intact from 5°C to 40°C
See the date indicated on the label or package.
P.A.O. (Period After Opening): 12 months when stored from 5°C to 40°C.

STERILITY

The packaged product is treated by Gammatom - a company specialized in sterilization treatments - with an irradiation dose of 25 kGy. The dose is identified following the validation of the sterilization process carried out by the Eurofins Laboratory according to the VdMax25 method required by the standard UNI EN ISO 11137-2.

TRACEABILITY

The color bottle is marked by an identifying batch (Lot Number) that allows complete traceability of the product, of the pigments used during the production phase and of the sterilization phase.

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PACKAGING

BIOTEK color is packaged in an airless container. This technology makes possible to optimally preserve the content as it does not come into contact with the air, it does not undergo variations and preserves its properties and sterility. An airless bottle has many advantages: greater safety thanks to the non-return valve and the double-chamber bottom; it reduces the use of preservatives in the product; it guarantees greater hygiene, in addition to the calibrated use of the product.

CORRECT USE OF THE PRODUCT

Directions for correct use:

- Shake well before use
- Do not use after the expiration date indicated on the bottle
- Do not pollute the content of the bottle
- Do not mix color
- The use must be in accordance with the intended purpose
- Do not mix the product with colors of other brands
- Keep out of reach of children
- Do not ingest and do not inhale
- Avoid contact with eyes
- Do not pour the used color back into the original bottle
- Do not use unlabeled bottles
- Do not use the product contained in a broken or defective bottle
- Store the product in a dry place at room temperature
- Keep away from heat sources
- Store in a dark environment
- Avoid freezing of the product
- Pour the color only in sterile capsules
- Do not use the sterile contents of the capsules on multiple patients
- Respect the operational hygiene protocol and the hygiene regulations of each country

Material Safety Data Sheet (MSDS) is provided for each reference of the BIOTEK line. The technical document takes into consideration the chemical substances and their mixtures regarding the physico-chemical, toxicological and environmental risk information, necessary for correct and safe handling of the mixtures.

What is declared in this Certificate of Conformity is a synthetic extract of the complete General BIOTEK Color Dossier *(Component Control File MO 70.02, Analysis Report, Project and Production File drawn up according to ISO 9001:2015)* available only to the Health Authorities upon specific request.



Milan, 01.01.2021

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DECLARATION OF CONFORMITY
PERMANENT MAKE-UP COLOR

TRADE NAME	BIOTEK
PRODUCT NAME	PARIS
PRODUCT CODE	E15S-08 15ml
DESCRIPTION	Mixture for use in tattoos or permanent make-up
PRODUCT USE	Professional use
MANUFACTURER	BIOTEK srl Milano Via R. Farneti 8 Italy P.I. IT10911780152
CONTACT	Tel +39.02.7380144 e-mail security@biotek.it
CONTENT	15ml / 0.5 fl.oz (nominal content)

HEREWITH DECLARE THAT

The product is original, designed and manufactured in Italy by BIOTEK laboratories - ISO 7 cleanroom.

The following Declaration of Conformity is issued by BIOTEK srl under sole responsibility as manufacturer of colors for permanent make-up. This product is intended for professional use only and may only be used by those with the appropriate qualifications that meet the necessary legal requirements established by each country.

The product is designed to perform PMU procedures, permanent make-up, semi-permanent make-up, dermopigmentation, micropigmentation, microblading, corrective aesthetic make-up, epidermal design and scalp pigmentation using adequate electrical or manual equipment suitable for the purpose.

BIOTEK adopts all possible precautions in the design, processing and packaging in order to guarantee a quality product. For this purpose, it has been adopted the ISO9001 Quality System and it has been a certified company since 2007 in the field of design and production processes whose mission is to guarantee customers safe and effective products.

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III LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRODUCTION PHASE
IV LEVEL - CLINICAL AND TOXICOLOGICAL TESTS
V LEVEL - STERILIZATION ISO 11137 / VDmax 25 Method
VI LEVEL - STABILITY TESTS OF FINAL PRODUCT
VII LEVEL - TRACEABILITY OF THE FINAL PRODUCT

BIOTEK declares compliance with current European and non-European regulations where the product has been placed on the market. In particular, it responds to the indications expressed in the (EU) Regulation of the European Commission of 14.12.2020 and in the amendments to Annex XVII of Regulation (EC) No. 1907/2006.

Substances falling within one or more of the following points:

(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:
- carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation
- reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation
- skin sensitiser category 1, 1A or 1B
- skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2
- serious eye damage category 1 or eye irritant category 2

(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*)

(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex

(d) substances listed in Appendix 13 to this Annex.

List of substances with specific concentration limits:

TABLE OF HEAVY METAL VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Mercury	231-106-7	7439-97-6	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Nickel	231-111-4	7440-02-0	0,0005 %	5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Organometallic tin	231-141-8	7440-31-5	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Antimony	231-146-5	7440-36-0	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Arsenic	231-148-6	7440-38-2	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Barium **	231-149-1	7440-39-3	0,05 %	500	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Cadmium	231-152-8	7440-43-9	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Chromium‡	231-157-5	7440-47-3	0,00005 %	0,5	0,02	UNI EN 71-3:2019	✓ COMPLIANT
Cobalt	231-158-0	7440-48-4	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Copper **	231-159-6	7440-50-8	0,025 %	250	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Zinc **	231-175-3	7440-66-6	0,2 %	2.000	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Lead	231-100-4	7439-92-1	0,00007 %	0,7	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Selenium	231-957-4	7782-49-2	0,0002 %	2	0,3	UNI EN 71-3:2019	✓ COMPLIANT
** Soluble Cromo‡ VI							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of heavy metals.

However, general precautions are recommended to ensure public safety.
Pigments must not be applied in case of allergy or intolerance to any of the ingredients shown on the label. The color may contain traces of Nickel and/or Chromium: it can cause allergic reactions. A sensitivity test should always be done before treatment. A positive reaction to the test requires a medical examination. Biotek assumes no responsibility for particular allergic reactions due to individual sensitivity towards colors.

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TABLE OF POLYCYCLIC-AROMATIC HYDROCARBONS VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % concentrazioni singole	0,5	0,2	AfPS GS 2014:01 PAK	✓ **COMPLIANT**
Benzo(a)pyrene	200-028-5	50-32-8	0,0000005%	0,005	0,0025	AfPS GS 2014:01 PAK	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Polycyclic-aromatic Hydrocarbons.

TABLE OF AROMATIC AMINES VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Methanol	200-659-6	67-56-1	11 %	110.000	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-anisidine **	201-963-1	90-04-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-toluidine **	202-429-0	95-53-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methyl-m- phenylenediamine **	202-453-1	95-80-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloroaniline **	203-401-0	106-47-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-thiodianiline **	205-370-9	139-65-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-naphthylamine**	202-080-4	91-59-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Aniline **	200-539-3	62-53-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Benzidine **	202-199-1	92-87-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-toluidine **	203-403-1	106-49-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-o-tolilazo-o-toluidine **	202-591-2	97-56-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methoxy-m- phenylenediamine **	210-406-1	615-05-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'- methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-amino-3-f luorophenol **	402-230-0	399-95-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,6-xylidine	201-758-7	87-62-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4-xylidine	202-440-0	95-68-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Aromatic Amines.

BIOTEK MILANO

TABLE OF ALLERGENIC AND CARCINOGENIC DYES VALUE

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Pigment Red 7 (PR7) CI 12420	229-315-3	6471-51-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 9 (PR9) CI 12460	229-104-6	6410-38-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 15 (PR15) CI 12465	229-105-1	6410-39-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 210 (PR210) CI 12477	612-766-9	61932-63-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 74 (PO74)		85776-14-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 65 (PY65) CI 11740	229-419-9	6528-34-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 74 (PY74) CI 11741	228-768-4	6358-31-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 12 (PR12) CI 12385	229-102-5	6410-32-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 14 (PR14) CI 12380	229-314-8	6471-50-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 17 (PR17) CI 12390	229-681-4	6655-84-1	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 112 (PR112) CI 12370	229-440-3	6535-46-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 14 (PY14) CI 21095	226-789-3	5468-75-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 55 (PY55) CI 21096	226-789-3	6358-37-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 2 (PR2) CI 12310	227-930-1	6041-94-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 22 (PR22) CI 12315	229-245-3	6448-95-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 146 (PR146) CI 12485	226-103-2	5280-68-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 269 (PR269) CI 12466	268-028-8	67990-05-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange16 (PO16) CI 21160	229-388-1	6505-28-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 1 (PY1) CI 11680	219-730-8	2512-29-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 12 (PY12) CI 21090	228-787-8	6358-85-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 87 (PY87) CI 21107:1	239-160-3	5110-84-6 14110-84-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 97 (PY97) CI 11767	235-427-3	12225-18-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 13 (PO13) CI 21110	222-530-3	3520-72-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 34 (PO34) CI 21115	239-898-6	15793-73-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 83 (PY83) CI 21108	226-939-8	5567-15-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 1 (SR1) CI 12150	214-968-9	1229-55-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Orange 24 (AO24) CI 20170	215-296-9	1320-07-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 23 (SR23) CI 26100	201-638-4	85-86-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 73 (AR73) CI 27290	226-502-1	5413-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 3 CI 11855	220-600-8	2832-40-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Green 16	603-214-8	12768-78-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 26	223-178-3	3761-53-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Violet 17	223-942-6	4129-84-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Basic Red 1	213-584-9	989-38-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 106	602-285-2	12223-01-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 124	612-788-9	61951-51-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 35	602-260-6	12222-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Orange 37	602-312-8	12223-33-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 1	220-704-3	2872-52-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 17	221-665-5	3179-89-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 9	228-919-4	6373-73-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 3	603-635-7	1325-82-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 39	264-654-0	64070-98-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Yellow 2	200-455-7	60-11-7	0,1 %»	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
** Solubile ‡Cromo VI.							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Allergenic and Carcinogenic Dyes.

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LABORATORIES

BIOTEK avails itself of the support of several authoritative analysis laboratories for the verification of colors compliance:

- *BUZZI* (Prato) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 052 L
- *EUROLAB* (Vicenza) Italy Accredited Analysis Laboratory ACCREDIA /LAB N° 0856L
- *CTL GmbH* (Bielefeld) Germany - International Laboratory specialized in tattoo and pmu color analysis
- *COMPLIFE* (Pavia) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 1318L - for toxicological analysis
- *EUROFINS BIOLAB (Milano)* Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 0085L - for Stability test and Validation of sterilization process Vdmax25

BIOTEK also makes use of other laboratories and authoritative research institutions such as:

- *University of Milan*
- *University of Studies of Pavia*

ANALYSIS METHODS

The laboratories selected by BIOTEK adopt different methods of analysis, applying the most suitable one in relation to the research to be carried out. In particular:

ANALISYS	METHODS
Determination of Aromatic Amines from Azo Dyes	UNI EN ISO 17234-1:2015 *(Leather)*
Determination of Polycyclic-Aromatic Hydrocarbons (PAH)	AfPS GS 2014:01
Determination of Heavy Metals	UNI EN 71-3:2019 (*Artificial Sweat Extraction)*
Determination of Allergenic and Carcinogenic Dyes	UNI EN 16373-2:2014 *(Textile)*

TOXICOLOGICAL INFORMATION

Extensive clinical tests are performed to support product quality and safety.
Cytotoxicity - Phototoxicity - Skin irritation - Intracutaneous reactivity

Toxicological data declare that the ingredients used for the production there are no related risk effects at concentrations under foreseeable conditions according to the indicated use.

INGREDIENTS

The ingredients are expressed on the label affixed to the bottle. The ingredients and wordings may vary depending on the regulations required by the country of destination.

DURATION

The BIOTEK color subjected to the *Accelerated Stability Study* and *Sterility Test ISO 11737-2:2009* maintains unchanged the qualitative and sterility parameters.
The shelf life of a closed packaged product can be determined in 5 years, when stored intact from 5°C to 40°C
See the date indicated on the label or package.
P.A.O. (Period After Opening): 12 months when stored from 5°C to 40°C.

STERILITY

The packaged product is treated by Gammatom - a company specialized in sterilization treatments - with an irradiation dose of 25 kGy. The dose is identified following the validation of the sterilization process carried out by the Eurofins Laboratory according to the VdMax25 method required by the standard UNI EN ISO 11137-2.

TRACEABILITY

The color bottle is marked by an identifying batch (Lot Number) that allows complete traceability of the product, of the pigments used during the production phase and of the sterilization phase.

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PACKAGING

BIOTEK color is packaged in an airless container. This technology makes possible to optimally preserve the content as it does not come into contact with the air, it does not undergo variations and preserves its properties and sterility. An airless bottle has many advantages: greater safety thanks to the non-return valve and the double-chamber bottom; it reduces the use of preservatives in the product; it guarantees greater hygiene, in addition to the calibrated use of the product.

CORRECT USE OF THE PRODUCT

Directions for correct use:

- Shake well before use
- Do not use after the expiration date indicated on the bottle
- Do not pollute the content of the bottle
- Do not mix color
- The use must be in accordance with the intended purpose
- Do not mix the product with colors of other brands
- Keep out of reach of children
- Do not ingest and do not inhale
- Avoid contact with eyes
- Do not pour the used color back into the original bottle
- Do not use unlabeled bottles
- Do not use the product contained in a broken or defective bottle
- Store the product in a dry place at room temperature
- Keep away from heat sources
- Store in a dark environment
- Avoid freezing of the product
- Pour the color only in sterile capsules
- Do not use the sterile contents of the capsules on multiple patients
- Respect the operational hygiene protocol and the hygiene regulations of each country

Material Safety Data Sheet (MSDS) is provided for each reference of the BIOTEK line. The technical document takes into consideration the chemical substances and their mixtures regarding the physico-chemical, toxicological and environmental risk information, necessary for correct and safe handling of the mixtures.

What is declared in this Certificate of Conformity is a synthetic extract of the complete General BIOTEK Color Dossier *(Component Control File MO 70.02, Analysis Report, Project and Production File drawn up according to ISO 9001:2015)* available only to the Health Authorities upon specific request.



Milan, 01.01.2021

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DECLARATION OF CONFORMITY
PERMANENT MAKE-UP COLOR

TRADE NAME	BIOTEK
PRODUCT NAME	MILAN
PRODUCT CODE	E15S-11 15ml
DESCRIPTION	Mixture for use in tattoos or permanent make-up
PRODUCT USE	Professional use
MANUFACTURER	BIOTEK srl Milano Via R. Farneti 8 Italy P.I. IT10911780152
CONTACT	Tel +39.02.7380144 e-mail security@biotek.it
CONTENT	15ml / 0.5 fl.oz (nominal content)

HEREWITH DECLARE THAT

The product is original, designed and manufactured in Italy by BIOTEK laboratories - ISO 7 cleanroom.

The following Declaration of Conformity is issued by BIOTEK srl under sole responsibility as manufacturer of colors for permanent make-up. This product is intended for professional use only and may only be used by those with the appropriate qualifications that meet the necessary legal requirements established by each country.

The product is designed to perform PMU procedures, permanent make-up, semi-permanent make-up, dermopigmentation, micropigmentation, microblading, corrective aesthetic make-up, epidermal design and scalp pigmentation using adequate electrical or manual equipment suitable for the purpose.

BIOTEK adopts all possible precautions in the design, processing and packaging in order to guarantee a quality product. For this purpose, it has been adopted the ISO9001 Quality System and it has been a certified company since 2007 in the field of design and production processes whose mission is to guarantee customers safe and effective products.

Quality has always been the center of BIOTEK production policy and, following the entry into force of the Regulation (EU) 2020/2081 - which amends Annex XVII of Regulation (EC) no. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) with regard to substances contained in inks for tattoos or permanent make-up - BIOTEK has implemented an internal protocol to validate the safety levels related to the raw materials used in the BIOTEK colors line production phases as follows:

Safety rating levels:

I LEVEL - RESEARCH OF AUTHORIZED AND/OR ALLOWED RAW MATERIALS
II LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRELIMINARY PRODUCTION PHASE
III LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRODUCTION PHASE
IV LEVEL - CLINICAL AND TOXICOLOGICAL TESTS
V LEVEL - STERILIZATION ISO 11137 / VDmax 25 Method
VI LEVEL - STABILITY TESTS OF FINAL PRODUCT
VII LEVEL - TRACEABILITY OF THE FINAL PRODUCT

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BIOTEK declares compliance with current European and non-European regulations where the product has been placed on the market. In particular, it responds to the indications expressed in the (EU) Regulation of the European Commission of 14.12.2020 and in the amendments to Annex XVII of Regulation (EC) No. 1907/2006.

Substances falling within one or more of the following points:

(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:
- carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation
- reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation
- skin sensitiser category 1, 1A or 1B
- skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2
- serious eye damage category 1 or eye irritant category 2

(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*)

(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex

(d) substances listed in Appendix 13 to this Annex.

List of substances with specific concentration limits:

TABLE OF HEAVY METAL VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Mercury	231-106-7	7439-97-6	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Nickel	231-111-4	7440-02-0	0,0005 %	5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Organometallic tin	231-141-8	7440-31-5	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Antimony	231-146-5	7440-36-0	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Arsenic	231-148-6	7440-38-2	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Barium **	231-149-1	7440-39-3	0,05 %	500	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Cadmium	231-152-8	7440-43-9	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Chromium‡	231-157-5	7440-47-3	0,00005 %	0,5	0,02	UNI EN 71-3:2019	✓ COMPLIANT
Cobalt	231-158-0	7440-48-4	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Copper **	231-159-6	7440-50-8	0,025 %	250	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Zinc **	231-175-3	7440-66-6	0,2 %	2.000	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Lead	231-100-4	7439-92-1	0,00007 %	0,7	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Selenium	231-957-4	7782-49-2	0,0002 %	2	0,3	UNI EN 71-3:2019	✓ COMPLIANT
** Soluble Cromo‡ VI							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of heavy metals.

However, general precautions are recommended to ensure public safety.
Pigments must not be applied in case of allergy or intolerance to any of the ingredients shown on the label. The color may contain traces of Nickel and/or Chromium: it can cause allergic reactions. A sensitivity test should always be done before treatment. A positive reaction to the test requires a medical examination. Biotek assumes no responsibility for particular allergic reactions due to individual sensitivity towards colors.

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TABLE OF POLYCYCLIC-AROMATIC HYDROCARBONS VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % concentrazioni singole	0,5	0,2	AfPS GS 2014:01 PAK	✓ **COMPLIANT**
Benzo(a)pyrene	200-028-5	50-32-8	0,0000005%	0,005	0,0025	AfPS GS 2014:01 PAK	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Polycyclic-aromatic Hydrocarbons.

TABLE OF AROMATIC AMINES VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Methanol	200-659-6	67-56-1	11 %	110.000	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-anisidine **	201-963-1	90-04-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-toluidine **	202-429-0	95-53-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methyl-m- phenylenediamine **	202-453-1	95-80-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloroaniline **	203-401-0	106-47-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-thiodianiline **	205-370-9	139-65-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-naphthylamine**	202-080-4	91-59-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Aniline **	200-539-3	62-53-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Benzidine **	202-199-1	92-87-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-toluidine **	203-403-1	106-49-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-o-tolilazo-o-toluidine **	202-591-2	97-56-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methoxy-m- phenylenediamine **	210-406-1	615-05-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'- methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-amino-3-f luorophenol **	402-230-0	399-95-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,6-xylidine	201-758-7	87-62-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4-xylidine	202-440-0	95-68-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Aromatic Amines.

BIOTEK MILANO

TABLE OF ALLERGENIC AND CARCINOGENIC DYES VALUE

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Pigment Red 7 (PR7) CI 12420	229-315-3	6471-51-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 9 (PR9) CI 12460	229-104-6	6410-38-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 15 (PR15) CI 12465	229-105-1	6410-39-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 210 (PR210) CI 12477	612-766-9	61932-63-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 74 (PO74)		85776-14-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 65 (PY65) CI 11740	229-419-9	6528-34-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 74 (PY74) CI 11741	228-768-4	6358-31-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 12 (PR12) CI 12385	229-102-5	6410-32-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 14 (PR14) CI 12380	229-314-8	6471-50-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 17 (PR17) CI 12390	229-681-4	6655-84-1	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 112 (PR112) CI 12370	229-440-3	6535-46-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 14 (PY14) CI 21095	226-789-3	5468-75-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 55 (PY55) CI 21096	226-789-3	6358-37-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 2 (PR2) CI 12310	227-930-1	6041-94-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 22 (PR22) CI 12315	229-245-3	6448-95-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 146 (PR146) CI 12485	226-103-2	5280-68-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 269 (PR269) CI 12466	268-028-8	67990-05-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange16 (PO16) CI 21160	229-388-1	6505-28-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 1 (PY1) CI 11680	219-730-8	2512-29-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 12 (PY12) CI 21090	228-787-8	6358-85-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 87 (PY87) CI 21107:1	239-160-3	5110-84-6 14110-84-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 97 (PY97) CI 11767	235-427-3	12225-18-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 13 (PO13) CI 21110	222-530-3	3520-72-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 34 (PO34) CI 21115	239-898-6	15793-73-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 83 (PY83) CI 21108	226-939-8	5567-15-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 1 (SR1) CI 12150	214-968-9	1229-55-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Orange 24 (AO24) CI 20170	215-296-9	1320-07-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 23 (SR23) CI 26100	201-638-4	85-86-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 73 (AR73) CI 27290	226-502-1	5413-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 3 CI 11855	220-600-8	2832-40-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Green 16	603-214-8	12768-78-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 26	223-178-3	3761-53-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Violet 17	223-942-6	4129-84-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Basic Red 1	213-584-9	989-38-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 106	602-285-2	12223-01-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 124	612-788-9	61951-51-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 35	602-260-6	12222-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Orange 37	602-312-8	12223-33-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 1	220-704-3	2872-52-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 17	221-665-5	3179-89-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 9	228-919-4	6373-73-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 3	603-635-7	1325-82-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 39	264-654-0	64070-98-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Yellow 2	200-455-7	60-11-7	0,1 %»	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
** Solubile ‡Cromo VI.							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Allergenic and Carcinogenic Dyes.

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LABORATORIES

BIOTEK avails itself of the support of several authoritative analysis laboratories for the verification of colors compliance:

- *BUZZI* (Prato) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 052 L
- *EUROLAB* (Vicenza) Italy Accredited Analysis Laboratory ACCREDIA /LAB N° 0856L
- *CTL GmbH* (Bielefeld) Germany - International Laboratory specialized in tattoo and pmu color analysis
- *COMPLIFE* (Pavia) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 1318L - for toxicological analysis
- *EUROFINS BIOLAB (Milano)* Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 0085L - for Stability test and Validation of sterilization process Vdmax25

BIOTEK also makes use of other laboratories and authoritative research institutions such as:

- *University of Milan*
- *University of Studies of Pavia*

ANALYSIS METHODS

The laboratories selected by BIOTEK adopt different methods of analysis, applying the most suitable one in relation to the research to be carried out. In particular:

ANALISYS	METHODS
Determination of Aromatic Amines from Azo Dyes	UNI EN ISO 17234-1:2015 *(Leather)*
Determination of Polycyclic-Aromatic Hydrocarbons (PAH)	AfPS GS 2014:01
Determination of Heavy Metals	UNI EN 71-3:2019 (*Artificial Sweat Extraction)*
Determination of Allergenic and Carcinogenic Dyes	UNI EN 16373-2:2014 *(Textile)*

TOXICOLOGICAL INFORMATION

Extensive clinical tests are performed to support product quality and safety.
Cytotoxicity - Phototoxicity - Skin irritation - Intracutaneous reactivity

Toxicological data declare that the ingredients used for the production there are no related risk effects at concentrations under foreseeable conditions according to the indicated use.

INGREDIENTS

The ingredients are expressed on the label affixed to the bottle. The ingredients and wordings may vary depending on the regulations required by the country of destination.

DURATION

The BIOTEK color subjected to the *Accelerated Stability Study* and *Sterility Test ISO 11737-2:2009* maintains unchanged the qualitative and sterility parameters.
The shelf life of a closed packaged product can be determined in 5 years, when stored intact from 5°C to 40°C
See the date indicated on the label or package.
P.A.O. (Period After Opening): 12 months when stored from 5°C to 40°C.

STERILITY

The packaged product is treated by Gammatom - a company specialized in sterilization treatments - with an irradiation dose of 25 kGy. The dose is identified following the validation of the sterilization process carried out by the Eurofins Laboratory according to the VdMax25 method required by the standard UNI EN ISO 11137-2.

TRACEABILITY

The color bottle is marked by an identifying batch (Lot Number) that allows complete traceability of the product, of the pigments used during the production phase and of the sterilization phase.

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PACKAGING

BIOTEK color is packaged in an airless container. This technology makes possible to optimally preserve the content as it does not come into contact with the air, it does not undergo variations and preserves its properties and sterility. An airless bottle has many advantages: greater safety thanks to the non-return valve and the double-chamber bottom; it reduces the use of preservatives in the product; it guarantees greater hygiene, in addition to the calibrated use of the product.

CORRECT USE OF THE PRODUCT

Directions for correct use:

- Shake well before use
- Do not use after the expiration date indicated on the bottle
- Do not pollute the content of the bottle
- Do not mix color
- The use must be in accordance with the intended purpose
- Do not mix the product with colors of other brands
- Keep out of reach of children
- Do not ingest and do not inhale
- Avoid contact with eyes
- Do not pour the used color back into the original bottle
- Do not use unlabeled bottles
- Do not use the product contained in a broken or defective bottle
- Store the product in a dry place at room temperature
- Keep away from heat sources
- Store in a dark environment
- Avoid freezing of the product
- Pour the color only in sterile capsules
- Do not use the sterile contents of the capsules on multiple patients
- Respect the operational hygiene protocol and the hygiene regulations of each country

Material Safety Data Sheet (MSDS) is provided for each reference of the BIOTEK line. The technical document takes into consideration the chemical substances and their mixtures regarding the physico-chemical, toxicological and environmental risk information, necessary for correct and safe handling of the mixtures.

What is declared in this Certificate of Conformity is a synthetic extract of the complete General BIOTEK Color Dossier *(Component Control File MO 70.02, Analysis Report, Project and Production File drawn up according to ISO 9001:2015)* available only to the Health Authorities upon specific request.



Milan, 01.01.2021

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DECLARATION OF CONFORMITY
PERMANENT MAKE-UP COLOR

TRADE NAME	BIOTEK
PRODUCT NAME	VENICE
PRODUCT CODE	E15S-14 15ml
DESCRIPTION	Mixture for use in tattoos or permanent make-up
PRODUCT USE	Professional use
MANUFACTURER	BIOTEK srl Milano Via R. Farneti 8 Italy P.I. IT10911780152
CONTACT	Tel +39.02.7380144 e-mail security@biotek.it
CONTENT	15ml / 0.5 fl.oz (nominal content)

HEREWITH DECLARE THAT

The product is original, designed and manufactured in Italy by BIOTEK laboratories - ISO 7 cleanroom.

The following Declaration of Conformity is issued by BIOTEK srl under sole responsibility as manufacturer of colors for permanent make-up. This product is intended for professional use only and may only be used by those with the appropriate qualifications that meet the necessary legal requirements established by each country.

The product is designed to perform PMU procedures, permanent make-up, semi-permanent make-up, dermopigmentation, micropigmentation, microblading, corrective aesthetic make-up, epidermal design and scalp pigmentation using adequate electrical or manual equipment suitable for the purpose.

BIOTEK adopts all possible precautions in the design, processing and packaging in order to guarantee a quality product. For this purpose, it has been adopted the ISO9001 Quality System and it has been a certified company since 2007 in the field of design and production processes whose mission is to guarantee customers safe and effective products.

Quality has always been the center of BIOTEK production policy and, following the entry into force of the Regulation (EU) 2020/2081 - which amends Annex XVII of Regulation (EC) no. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) with regard to substances contained in inks for tattoos or permanent make-up - BIOTEK has implemented an internal protocol to validate the safety levels related to the raw materials used in the BIOTEK colors line production phases as follows:

Safety rating levels:

I LEVEL - RESEARCH OF AUTHORIZED AND/OR ALLOWED RAW MATERIALS
II LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRELIMINARY PRODUCTION PHASE
III LEVEL - MAPPING AND CHEMICAL ANALYSIS OF PIGMENTS - PRODUCTION PHASE
IV LEVEL - CLINICAL AND TOXICOLOGICAL TESTS
V LEVEL - STERILIZATION ISO 11137 / VDmax 25 Method
VI LEVEL - STABILITY TESTS OF FINAL PRODUCT
VII LEVEL - TRACEABILITY OF THE FINAL PRODUCT

BIOTEK declares compliance with current European and non-European regulations where the product has been placed on the market. In particular, it responds to the indications expressed in the (EU) Regulation of the European Commission of 14.12.2020 and in the amendments to Annex XVII of Regulation (EC) No. 1907/2006.

Substances falling within one or more of the following points:

(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:
- carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation
- reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation
- skin sensitiser category 1, 1A or 1B
- skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2
- serious eye damage category 1 or eye irritant category 2

(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*)

(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex

(d) substances listed in Appendix 13 to this Annex.

List of substances with specific concentration limits:

TABLE OF HEAVY METAL VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Mercury	231-106-7	7439-97-6	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Nickel	231-111-4	7440-02-0	0,0005 %	5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Organometallic tin	231-141-8	7440-31-5	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Antimony	231-146-5	7440-36-0	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Arsenic	231-148-6	7440-38-2	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Barium **	231-149-1	7440-39-3	0,05 %	500	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Cadmium	231-152-8	7440-43-9	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Chromium‡	231-157-5	7440-47-3	0,00005 %	0,5	0,02	UNI EN 71-3:2019	✓ COMPLIANT
Cobalt	231-158-0	7440-48-4	0,00005 %	0,5	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Copper **	231-159-6	7440-50-8	0,025 %	250	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Zinc **	231-175-3	7440-66-6	0,2 %	2.000	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Lead	231-100-4	7439-92-1	0,00007 %	0,7	0,3	UNI EN 71-3:2019	✓ COMPLIANT
Selenium	231-957-4	7782-49-2	0,0002 %	2	0,3	UNI EN 71-3:2019	✓ COMPLIANT
** Soluble Cromo‡ VI							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of heavy metals.

However, general precautions are recommended to ensure public safety.
Pigments must not be applied in case of allergy or intolerance to any of the ingredients shown on the label. The color may contain traces of Nickel and/or Chromium: it can cause allergic reactions. A sensitivity test should always be done before treatment. A positive reaction to the test requires a medical examination. Biotek assumes no responsibility for particular allergic reactions due to individual sensitivity towards colors.

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TABLE OF POLYCYCLIC-AROMATIC HYDROCARBONS VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % concentrazioni singole	0,5	0,2	AfPS GS 2014:01 PAK	✓ **COMPLIANT**
Benzo(a)pyrene	200-028-5	50-32-8	0,0000005%	0,005	0,0025	AfPS GS 2014:01 PAK	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Polycyclic-aromatic Hydrocarbons.

TABLE OF AROMATIC AMINES VALUES

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Methanol	200-659-6	67-56-1	11 %	110.000	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-anisidine **	201-963-1	90-04-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
o-toluidine **	202-429-0	95-53-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methyl-m- phenylenediamine **	202-453-1	95-80-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloroaniline **	203-401-0	106-47-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-thiodianiline **	205-370-9	139-65-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-naphthylamine**	202-080-4	91-59-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Aniline **	200-539-3	62-53-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Benzidine **	202-199-1	92-87-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-toluidine **	203-403-1	106-49-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-o-tolilazo-o-toluidine **	202-591-2	97-56-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-methoxy-m- phenylenediamine **	210-406-1	615-05-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'- methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
4-amino-3-f luorophenol **	402-230-0	399-95-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,6-xylidine	201-758-7	87-62-7	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**
2,4-xylidine	202-440-0	95-68-1	0,0005 %	5	1	UNI EN 17234-1:2015	✓ **COMPLIANT**

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Aromatic Amines.

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BIOTEK MILANO

TABLE OF ALLERGENIC AND CARCINOGENIC DYES VALUE

Substance name	EC No	CAS No	REACH Limit value concentration Weight %	REACH Limit value concentration Weight ppm	LOQ Limit of quantification ppm	Analysis Method	CONFORMITY BIOTEK COLOR
Pigment Red 7 (PR7) CI 12420	229-315-3	6471-51-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 9 (PR9) CI 12460	229-104-6	6410-38-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 15 (PR15) CI 12465	229-105-1	6410-39-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 210 (PR210) CI 12477	612-766-9	61932-63-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 74 (PO74)		85776-14-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 65 (PY65) CI 11740	229-419-9	6528-34-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 74 (PY74) CI 11741	228-768-4	6358-31-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 12 (PR12) CI 12385	229-102-5	6410-32-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 14 (PR14) CI 12380	229-314-8	6471-50-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 17 (PR17) CI 12390	229-681-4	6655-84-1	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 112 (PR112) CI 12370	229-440-3	6535-46-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 14 (PY14) CI 21095	226-789-3	5468-75-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 55 (PY55) CI 21096	226-789-3	6358-37-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 2 (PR2) CI 12310	227-930-1	6041-94-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 22 (PR22) CI 12315	229-245-3	6448-95-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 146 (PR146) CI 12485	226-103-2	5280-68-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Red 269 (PR269) CI 12466	268-028-8	67990-05-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange16 (PO16) CI 21160	229-388-1	6505-28-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 1 (PY1) CI 11680	219-730-8	2512-29-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 12 (PY12) CI 21090	228-787-8	6358-85-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 87 (PY87) CI 21107:1	239-160-3	5110-84-6 14110-84-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 97 (PY97) CI 11767	235-427-3	12225-18-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 13 (PO13) CI 21110	222-530-3	3520-72-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Orange 34 (PO34) CI 21115	239-898-6	15793-73-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Yellow 83 (PY83) CI 21108	226-939-8	5567-15-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 1 (SR1) CI 12150	214-968-9	1229-55-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Orange 24 (AO24) CI 20170	215-296-9	1320-07-6	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Red 23 (SR23) CI 26100	201-638-4	85-86-9	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 73 (AR73) CI 27290	226-502-1	5413-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 3 CI 11855	220-600-8	2832-40-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Green 16	603-214-8	12768-78-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Red 26	223-178-3	3761-53-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Acid Violet 17	223-942-6	4129-84-4	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Basic Red 1	213-584-9	989-38-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 106	602-285-2	12223-01-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 124	612-788-9	61951-51-7	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Blue 35	602-260-6	12222-75-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Orange 37	602-312-8	12223-33-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 1	220-704-3	2872-52-8	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Red 17	221-665-5	3179-89-3	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Disperse Yellow 9	228-919-4	6373-73-5	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 3	603-635-7	1325-82-2	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Pigment Violet 39	264-654-0	64070-98-0	0,1 %	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
Solvent Yellow 2	200-455-7	60-11-7	0,1 %»	1.000	50	UNI EN 16373-2:2014	✓ **COMPLIANT**
** Solubile ‡Cromo VI.							

BIOTEK color complies with the concentration limit values expressed in Appendix 13 Item 75 - List of substances with specific concentration limits with particular reference to the presence of Allergenic and Carcinogenic Dyes.

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LABORATORIES

BIOTEK avails itself of the support of several authoritative analysis laboratories for the verification of colors compliance:

- *BUZZI* (Prato) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 052 L
- *EUROLAB* (Vicenza) Italy Accredited Analysis Laboratory ACCREDIA /LAB N° 0856L
- *CTL GmbH* (Bielefeld) Germany - International Laboratory specialized in tattoo and pmu color analysis
- *COMPLIFE* (Pavia) Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 1318L - for toxicological analysis
- *EUROFINS BIOLAB (Milano)* Italy - Accredited Analysis Laboratory ACCREDIA /LAB N° 0085L - for Stability test and Validation of sterilization process Vdmax25

BIOTEK also makes use of other laboratories and authoritative research institutions such as:

- *University of Milan*
- *University of Studies of Pavia*

ANALYSIS METHODS

The laboratories selected by BIOTEK adopt different methods of analysis, applying the most suitable one in relation to the research to be carried out. In particular:

ANALISYS	METHODS
Determination of Aromatic Amines from Azo Dyes	UNI EN ISO 17234-1:2015 *(Leather)*
Determination of Polycyclic-Aromatic Hydrocarbons (PAH)	AfPS GS 2014:01
Determination of Heavy Metals	UNI EN 71-3:2019 (*Artificial Sweat Extraction)*
Determination of Allergenic and Carcinogenic Dyes	UNI EN 16373-2:2014 *(Textile)*

TOXICOLOGICAL INFORMATION

Extensive clinical tests are performed to support product quality and safety.
Cytotoxicity - Phototoxicity - Skin irritation - Intracutaneous reactivity

Toxicological data declare that the ingredients used for the production there are no related risk effects at concentrations under foreseeable conditions according to the indicated use.

INGREDIENTS

The ingredients are expressed on the label affixed to the bottle. The ingredients and wordings may vary depending on the regulations required by the country of destination.

DURATION

The BIOTEK color subjected to the *Accelerated Stability Study* and *Sterility Test ISO 11737-2:2009* maintains unchanged the qualitative and sterility parameters.
The shelf life of a closed packaged product can be determined in 5 years, when stored intact from 5°C to 40°C
See the date indicated on the label or package.
P.A.O. (Period After Opening): 12 months when stored from 5°C to 40°C.

STERILITY

The packaged product is treated by Gammatom - a company specialized in sterilization treatments - with an irradiation dose of 25 kGy. The dose is identified following the validation of the sterilization process carried out by the Eurofins Laboratory according to the VdMax25 method required by the standard UNI EN ISO 11137-2.

TRACEABILITY

The color bottle is marked by an identifying batch (Lot Number) that allows complete traceability of the product, of the pigments used during the production phase and of the sterilization phase.

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PACKAGING

BIOTEK color is packaged in an airless container. This technology makes possible to optimally preserve the content as it does not come into contact with the air, it does not undergo variations and preserves its properties and sterility. An airless bottle has many advantages: greater safety thanks to the non-return valve and the double-chamber bottom; it reduces the use of preservatives in the product; it guarantees greater hygiene, in addition to the calibrated use of the product.

CORRECT USE OF THE PRODUCT

Directions for correct use:

- Shake well before use
- Do not use after the expiration date indicated on the bottle
- Do not pollute the content of the bottle
- Do not mix color
- The use must be in accordance with the intended purpose
- Do not mix the product with colors of other brands
- Keep out of reach of children
- Do not ingest and do not inhale
- Avoid contact with eyes
- Do not pour the used color back into the original bottle
- Do not use unlabeled bottles
- Do not use the product contained in a broken or defective bottle
- Store the product in a dry place at room temperature
- Keep away from heat sources
- Store in a dark environment
- Avoid freezing of the product
- Pour the color only in sterile capsules
- Do not use the sterile contents of the capsules on multiple patients
- Respect the operational hygiene protocol and the hygiene regulations of each country

Material Safety Data Sheet (MSDS) is provided for each reference of the BIOTEK line. The technical document takes into consideration the chemical substances and their mixtures regarding the physico-chemical, toxicological and environmental risk information, necessary for correct and safe handling of the mixtures.

What is declared in this Certificate of Conformity is a synthetic extract of the complete General BIOTEK Color Dossier *(Component Control File MO 70.02, Analysis Report, Project and Production File drawn up according to ISO 9001:2015)* available only to the Health Authorities upon specific request.



Milan, 01.01.2021

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