



To all BIP customers

Türkenfeld, 03.08.2026

Customer declaration on REACH, RoHS, Latex

Dear Customer,

REACH

We hereby inform you that only the following articles supplied by us contain a substance of very high concern on the SVHC candidate list (since January 2024) above 0.1 % according to Art. 33 of the REACH Regulation (Regulation (EC) No. 1907/2006):

Articles affected:

Plastic components including needle overmolding (cannula, stylet, mandrel) of all BIP medical devices of the following product groups:

- Biopsy Devices, disposable – only pre-mounted coaxial cannula in type HC-TX (upon LOT 0325)
- Biopsy Needles (upon LOT 1224)
- Fine Biopsy Needles (upon LOT 0325)
- Coaxial Cannulas (upon LOT 0325)
- Marking Clips (upon LOT 0325)
- Localization Wires (upon LOT 0325)

SVHC substance identification:

UV-239, 2-(2-Hydroxy-5-tert-octylphenyl)benzotriazol
CAS-Nr.: 3147-75-9, EU-Liste Nr.: 221-573-5

Concentration in mixture in the articles:

≥ 0.1 - < 0.3 [wt%]

Classification:

vPvB = very persistent and very bioaccumulative

Geschäftsführer

Thomas Heske

Tel.: +49 (0)8193-9318-0

Fax: +49 (0)8193-6548

info@bipmedical.com

Kontakt

Am Brand 1

82299 Türkenfeld

Germany

www.bipmedical.com

Registergericht München

HRB 88041

USt-ID DE128218247

Bankverbindungen

Commerzbank AG München

IBAN DE57 7008 0000 0697 5690 00

BIC DRESDEFF700

VR-Bank Fürstenfeldbruck eG

IBAN DE45 7016 3370 0000 2010 30

BIC GENODEF1FFB



Hazard statements:

EUH441 = Highly bioaccumulative in the environment and in living organisms, including humans

Note: The concentration of 0.1 % - 0.3 % weight by weight (w/w) of this SVHC in our articles poses no risk to humans or the environment when handled properly and does not restrict the safe use of BIP medical devices. The articles concerned do not come into contact with patients when used as intended.

Precautionary statements:

P273 = Avoid release to the environment

P501 = Dispose of in accordance with local regulations

Environmental information:

Do not allow to enter waterways, wastewater, or soil.

Disposal instructions:

- Dispose of in accordance with all applicable international, national, and local laws, regulations, and statutes.
- When disposing of within the EU, use the applicable waste code according to the European Waste Catalogue (EWC).

Our suppliers are obliged either by law or by contract to inform us without request if the products they supply contain a SVHC substance above 0.1 %.

If we receive information in this regard from our suppliers and thereby become aware that the 0.1 % weight by weight limit for a SVHC substance is exceeded in articles in our sales products, we will update this REACH declaration.

Accordingly, all other sales products from BIP GmbH are free from substances on the current SVHC candidate list (as of 03-Aug-2026).

The data has been compiled to the best of our knowledge. However, we are dependent on the assistance of our suppliers with regard to the completeness of data.

RoHS

Our Medical devices do not fall under the RoHS directive, as they do not contain electrics / electronics.

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Latex

Our Medical devices and the articles they contain do not contain latex or latex-based compounds. This declaration applies to all materials used in the manufacture and packaging of our products.

Kind regards,

— Thomas Heske
Managing Director (CEO)

Geschäftsführer

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