Polypropylene

Bormed™ BJ868MO

We confirm that this product fulfils the requirements on materials used for the manufacturing of articles or components of articles intended for medical use as described in:

Council of Europe European Pharmacopoeia:

Material is not compliant to Ph. Eur Monograph 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations or Monograph 3.1.3. Polyolefins. It contains additive(s) not listed in the monographs. Such additives can be used if authorised and justified, the specification and authorisation being the responsibility of the end user. Borealis can provide support by disclosing, subject to concluding a Secrecy Agreement,

the formulation of the resin to enable the assessments to be completed. Please

contact your Borealis or Borouge representatives for assistance.

Germany The product follows the VDI 2017 Guideline on "Medical Grade Plastic" that

covers the requirements for change management, quality management, supply

security and support for regulatory requirements.

USA Material has passed the following United States Pharmacopeia tests:

Biological reactivity tests - in vitro <87>: Cytotoxicity (Elution test)

Biological reactivity tests - in vivo <88>: Class VI - 70 °C

Plastic materials of construction <661.1>: Identification, physicochemical and extractable metals (as listed in the chapter) tests. Plastic additive tests are done

according to Borealis' internal methods.

Tests are made according to the current Pharmacopeia edition at the time of the

testing (USP-NF 2022).

Additional testing Material has been tested according to the following ISO 10993 biological tests, in

the extent applicable for polymer pellets:

Cytotoxicity (ISO 10993-5)

Acute systemic toxicity (ISO 10993-11)

Skin irritation / intracutaneous reactivity (ISO 10993-10)

Dermal sensitization (ISO 10993-10) Hemocompatibility (ISO 10993-4)

Tests are made according to the current ISO 10993 edition at the time of the

testing (2022).

Elemental impurities During the manufacturing process of this product, we neither use nor intentionally

incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D(R2)

Guideline on Elemental Impurities (May 2022).

DMF number Material has been assigned the FDA Drug Master File number(s):

DMF 033438

or modification of Bormed grades, such pre-notice period needs to be included in

Technical Delivery Specifications.

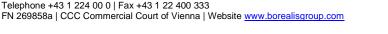
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Prepared by Borealis, Group Product Stewardship

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Disclaimer

The product(s) mentioned herein are not intended for use as medical implant material or implantable medical devices and we do not support their use for such applications.

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