STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

08.04.2024 Ed. 11

Polypropylene
Bormed™ RG835MO

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 tests (with exception of absorbance and total organic carbon tests; please contact your Borealis or Borouge representatives for additional information), and extractable metals tests (as listed in the chapter). 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 031608
Additional information	If a customer wishes to take advantage of the pre-notice period in case of deletion or modification of Bormed grades, such pre-notice period needs to be included in Technical Delivery Specifications. This edition of the document supersedes any previous editions. Borealis reserves the right to modify this document at any time, so please ensure to view it frequently. Changes to this document may be made with or without notice. Please always ensure that you are viewing the latest edition by downloading documents directly from our website at www.borealisgroup.com.
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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.

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however we do not assume any liability whatsoever for the accuracy and completeness of such information.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

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