



MEDAN
GROUP

MATERIAL SPECIFICATION

Rev.:
00

Material code: MS0061

Material type:

PC

Material name:

MAKROLON 2458

Supplier:

COVESTRO

STERILIZATION

STERILIZATION

EtO, Irradiation or Autoclave compatible

General Compliance Information

REACH DECLARATION (ANNEX XVII)

Substances under restriction are not contained (Annex XVII List of July 15th, 2020)

ROHS Restriction Directive 2011/65/EU

Compliant

ROHS Restriction Directive 2015/863

Compliant

CLP Classification on according to 1272/2008 (Regulation)

No classification in according with the Regulation (EC) N° 1272/ 2008

Biocompatibility information

USP VI

Compliant

ISO 10993

Genotoxicity-3/ Haemocompatibility-4/ Cytotoxicity-5/ Implantation-6/ Sensitization-10/ Irritation & Intracutaneous reactivity-10/ Systemic toxicity & Pyrogenicity-11

Pharmacopoeia information

European Regulations

8th Edition

USP VI

USP <661.1>

SVHC (Substances of Very High Concern) (REACH Regulation 1907/2006 Article 59)

SVHC (Art. 59 REACH Regulation 1907/2006)

Not contained

PHthalATES

Not contained

BPA

Contained less than 0.1 % weight by weight of residual BPA

Other substances

BSE/ TSE

Contains animal substances in accordance with EU Regulations: 142/ 2011/ EC

CONFLICT MINERALS

Not contained

PFOA

These substances were not intentionally added

LATEX

Not contained

HEAVY METALS

Not contained

OZONE Depleting Substances

Not contained

Please, be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements
Medan Group does not test or analyze this material for any specified regulatory requirements nor for any technical data.
Medan Group shall not be liable in case of deviations related to performed tests that could be contradictory with the provided information in this material datasheet.
The sterilization data are provided for informative purposes only. The sterilization stability must be validated by the customer and/or the end user.