

CERTIFICATE



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Issued by

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Product

MABS

Grade

TR580

Issue date

February 17, 2016

Information of Chemicals

- Chemical Product Name : MABS Resin
- Use : Medical application (Various connectors)
- Chemical Type : Thermoplastics
- MSDS Information : www.chemwide.com

Certificate

- TR580 is in compliance with Pharmacopoeia and Biocompatibility-Tests in Europe and United States as specified below.
However, biocompatibility tests were recorded on tests specimens of TR580 to show compatibility of the material in general. The biocompatibility-tests listed below are not part of any continuous production control.
- US Pharmacopoeia Biological Reactivity Tests, USP Plastic Class VI (USP VI)
ISO 10993-3 Biological Evaluation of Medical Devices Part 3
: Tests for Genotoxicity
ISO 10993-4 Biological Evaluation of Medical Devices Part 4
: Tests for Hemocompatibility
ISO 10993-5 Biological Evaluation of Medical Devices Part 5
: Test for Cytotoxicity
ISO 10993-10 Biological Evaluation of Medical Devices Part 10
: Test for Irritation or intracutaneous reactivity
ISO 10993-11 Biological Evaluation of Medical Devices Part 11
: Test for Systemic toxicity

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