



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. **G1 18 05 23355 020**

Manufacturer: **Barkey GmbH & Co. KG**

Gewerbestr. 8
33818 Leopoldshöhe
GERMANY



Facility(ies):

Barkey GmbH & Co. KG
Gewerbestr. 8, 33818 Leopoldshöhe, GERMANY

Product

Category(ies):

Blood warmer
Fresh-Frozen-Plasma thawing devices
Fluid and infusion warmer
Warming devices for patients
Dry-warming device for the pasteurizing
of mother's milk

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713127236

Valid from: 2018-07-11

Valid until: 2023-07-10



Date, 2018-05-25

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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