

EC Declaration of Conformity SAHARA 4

Manufacturer: TRANSMED Medizintechnik GmbH & Co. KG

Manufacturer SRN: DE-MF-000005859

Basic UDI-DI: 4028339BPAS4Q5

Product type: SAHARA 4
Product name: SAHARA 4
Product code: 97.8720.500

Intended purpose: Thawing and warming of blood products packed in plastic bags prior to transfusion

Risk class:

acc. to MDR, Annex VIII

Scope of application: All

We herewith declare under our sole responsibility that the above mentioned product(s) meet the provisions of the following Directives and Regulations.

Applicable EU Directives and Regulations:

REGULATION (EU) 2017/745 (MDR) of 5 April 2017 on medical devices and COUNCIL DIRECTIVE 2006/42/EC of 17 May 2006 on machinery

DIRECTIVE 2011/65/EU of 8 June 2011 concerning the Restriction of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

Applied standards or common specifications:

see Product Specification in Technical Documentation

MDR Conformity Assessment Route: Annex II and III

Valid until: 2026-05-31

Place, Date: Bad Wünnenberg, 2021-06-01

Signature: Dipl.-Ing. Wolfgang Henze

Position: Authorized Representative