



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 019502 0068 Rev. 01

Manufacturer:

Haemonetics Corporation

400 Wood Road
Braintree MA 02184
USA

Product Category(ies): Automated Cell Collection Products (Red Cell, Platelet, Plasma Therapeutics); Blood Management Products (Autologous Cell Salvage, Cell Washing, Suction, Filtering, Rapid Infusion, Freezing & Thawing); Blood Bags and Blood Component Collection Systems, Blood Processing Systems, Blood Filtration Systems and Related Accessories, including Products Containing Anticoagulants and Preservatives; Medical Filters including Extracorporeal and Blood Filters; Stand Alone Blood Management Software Products

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.:

B021-515 / 72152113-1

Valid from:

2020-04-14

Valid until:

2024-05-26

Date,

2020-04-14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

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Christoph Dicks
Head of Certification/Notified Body



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