



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

60 pd



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 071750 0024 Rev. 00

Manufacturer:

Haemonetics S.A.

Signy Centre
Rue des Fléchères 6
1274 Signy-Centre
SWITZERLAND

Product Category(ies): Automated Cell Collection Products (Red Blood Cell, Platelet, Plasma Therapeutics: Pre-connected Plasma Collection Sets with Blow Molded Bowls, Plasma Collection Bags and Harness Sets) and Standalone Blood, Cell & Tissue 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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10717500024Rev.00

Report No.: 72162793

Valid from: 2021-04-13

Valid until: 2024-05-26

Date, 2021-04-13

Christoph Dicks
Head of Certification/Notified Body