ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD
Product Service

EC Certificate

EC Design-Examination Certificate

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

No. G7 17 04 74018 017

Manufacturer:
CERUS Corporation
2550 Stanwell Drive
Concord CA 94520
USA

EC-Representative:
Cerus Europe B.V.
Stationsstraat 79-D
3811 MH Amersfoort
THE NETHERLANDS

Product:
Blood Processing Devices
Pathogen Inactivation Disposables

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713095262

Valid from: 2017-05-30
Valid until: 2022-05-29

Date, 2017-05-08

Stefan Preiß

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

TÜV®

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No. G7 17 04 74018 017

Model(s):

INTERCEPT
(Amotosalen Photochemical Treatment)
Blood System for Platelets

Parameters:

- INTERCEPT Processing Set for Small Volume Platelet Units (INT21)
- INTERCEPT Processing Set for Large Volume Platelet Units (INT22)
- INTERCEPT Platelet Processing Set with Dual Storage Containers (INT25)
- INTERCEPT Platelet Processing Set with Triple Storage Containers (INT26)

Facility(ies):

Cerus Europe B.V.
Stationsstraat 79-D, 3811 MH Amersfoort, THE NETHERLANDS

CERUS Corporation
2550 Stanwell Drive, Concord CA 94520, USA

Cerus Corporation
2411 Stanwell Drive, Concord CA 94520, USA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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