ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

CERTIFICATE

No. QS6 104026 0003 Rev. 00

Certificate Holder: **Diasoft B.V.**
Klepelhoek 11
3833 GZ Leusden
THE NETHERLANDS

Certification Mark:

Scope of Certificate: **Design, Development and Manufacture of Software and Interface Equipment for Dialysis Treatment and Administration; The Provision of User Training of Dialysis Treatment and Administration Software**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **40-808-0026**

Effective Date: **2020-07-09**

Expiry Date: **2022-04-23**

Date of Issue: 2020-07-10

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 104026 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies):
Diasoft B.V.
Klepelhoek 11, 3833 GZ Leusden, THE NETHERLANDS

Facility Scopes:
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