



EC CERTIFICATE

Diasoft BV

Klepelhoek 11
Leusden 3833 GZ THE NETHERLANDS

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design, development and production of software and interface equipment for dialysis treatment and administration

Device Classifications:

Class IIb

Device Descriptions and Model Type:

Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number A17127
Certificate Number 622.160424
Initial Issue Date April 23, 2010

Cycle Start Date April 24, 2016
Effective Date April 24, 2016
Expiry Date April 23, 2019

Authorised by

Paul Daysh

Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



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Status: [here](#)

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Software	Dialysis treatment and administration software	Diamant II, SmartConnector and Mini SmartConnector	Class IIb	-

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