Manufacturers declaration of conformity

(Directive 93/42/EEC)

Manufacturer

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Device

Diamant II version 3.9 - Dialysis Software and SmartConnector connectivity hardware

Scope

1. Design, development and production of software for renal patient treatment, administration and workflow management
2. Design, development and production of hardware for medical equipment data connectivity and workflow management

The product described above is in conformity with Annex II for class IIb (rule 11) of the Medical Device Directive 93/42/EEC as transported into national legislation.

I, the undersigned, hereby declare that the device specified above conforms to the above mentioned Directive.

Complies with additional standards: EN - IEC 62304
EN - IEC 60601

Full name: J. van den Berge
Position: Business unit manager
Signature:

Date of issue: 26 August 2015