



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 18 04 33226 013

Manufacturer: **SINED s.r.l.**
Via Ferrarese 219/7
40128 Bologna
ITALY



Facility(ies): SINED s.r.l.
Via Ferrarese 219/7, 40128 Bologna, ITALY

Product Category(ies): **Software for dialysis Patient monitoring**

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. See also notes overleaf.

Report No.: ITA1083988

Valid from: 2018-06-11
Valid until: 2023-06-10



Date, 2018-05-25

S. Preiß
Stefan Preiß

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

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