



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 81830 005

Manufacturer: Clinical Laserthermia System AB
Scheelevägen 2
223 81 Lund
SWEDEN



Facility(ies): Clinical Laserthermia System AB
Scheelevägen 2, 223 81 Lund, SWEDEN

Product Category(ies): Medical laser Systems(laser unit, temperature sensors, laser applicator and introducer set) for immunostimulating treatment of solid cancer Tumors and for other surgical applications

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.: 713124681

Valid from: 2018-04-30

Valid until: 2023-04-29



Date, 2018-02-23

Stefan Preiß

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

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