



Product Service

Confirmation Statement on device(s) covered by EU Quality Management System Certificate (MDR)

No. GRD 127759 0004 Rev. 00

Manufacturer:

ISD MEDITECH SDN BHD

No. 3, Jalan PJS 3/2, Taman Medan
46000 Petaling Jaya, Selangor
MALAYSIA

This Confirmation Statement confirms device(s) covered by the aforementioned EU Quality Management System Certificate (MDR). It considers clarification of device(s) covered by the device group(s). For details and confirmation statement validity see:

www.tuvsud.com/ps-cert?q=cert:GRD 127759 0004 Rev. 00

Report No.:

MAL-721434747

Christoph Dicks

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Head of Certification/Notified Body

Isd Meditech

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Device(s):

Thermal Paper Recording for Electrocardiography (ECG), and Cardiotocography (CTG)

The involvement of the notified bodies is limited to the aspect relating to conformity of the devices with the metrological requirements

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