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Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 010393 0536 Rev. 00

Manufacturer:

CODAN Medizinische Geräte GmbH
Stig Husted-Andersen Strasse 11
23738 Lensahn
GERMANY

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 010393 0533 Rev. 02

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply.

Report No.: 713269119

Valid until: 2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2023-01-02

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pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 010393 0536 Rev. 00

Product Category(ies): **Sterile and Non-Sterile Single-Use Medical Devices for Infusion and Transfusion Therapy, Irrigation Sets for Urology and Gynaecology as well as Mixing and Withdraw Products**

Description of Change:

Change of manufacturers legal form to CODAN Medizinische Geräte GmbH with the internal company structure change to outsource the manufacturing and support processes to the facility CODAN Medizinische Polymertechnologie GmbH.

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