intertek
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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Mediplast AB

Bronsåldersgatan 2, SE-213 76 Malmö, Sweden

Product Category:

- Class I Sterile devices
- Class IIa sterile sets
- Surgical swabs, sponges and temponades
- Cannulas and Needles
- Respiratory Devices, non-active
- Urological Devices
- Suction Devices, non-active accessories
- Tubing
- Suction catheters
- Transfusion/Infusion Devices
- ENT Devices
- Wound Drains
- Sponges, Bandages and wound dressings

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41311518-03

Initial Certification Date:
10 June 1998

Certificate Valid from:
25 May 2021

Certificate Expiry Date:
10 June 2023

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

25 May 2021
Signed Date

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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.