



EU Quality Management System Certificate ES23/00000293

The management system of

PROHS Equipamento Hospitalar e Serviços Associados S.A.

Rua do Castanhal 316 - Zona Industrial Maia I, sector II, Maia, 4475-122, Portugal

SRN: PT-MF-000002798

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 05 February 2024 until 23 March 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 23 September 2027
Issue 3. Certified since 23 March 2023

Authorised by
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PROHS Equipamento Hospitalar e Serviços Associados S.A.

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa devices

Horizontal steam sterilizer for the sterilization of invasive and non-invasive medical devices (Codes: MDA 0317, MDS 1004, MDS 1009; Basic UDI-DI: 5604425SSPFF) :

- Family Full Jacket: FJ 70L 1/2 PD (32*32*70), FJ 100L 1/2 PD (32*32*100), FJ 110L 1/2 PD (40*40*70), FJ 145L 1/2 PD (40*40*90), FJ 175L 1/2 PD (50*50*70), FJ 250L 1/2 PD (50*50*100), FJ 340L 1/2 PD (70*70*70), FJ 360L 1/2 PD (60*60*100), FJ 490L 1/2 PD (70*70*100), FJ 610L 1/2 PD (70*70*125), FJ 640L 1/2 PD (70*70*130), FJ 740L 1/2 PD (70*70*150), FJ 780L 1/2 PD (70*70*160), FJ 930L 1/2 PD (70*70*190).
- Family Partial Jacket: PJ 190L 1/2 PD (50*50*75), PJ 250L 1/2 PD (50*50*100), PJ 325L 1/2 PD (50*50*130), PJ 350L 1/2 PD (68*68*75), PJ 360L 1/2 PD (60*60*100), PJ 460L 1/2 PD (68*68*100), PJ 600L 1/2 PD (68*68*130), PJ 740L 1/2 PD (68*68*160), PJ 880L 1/2 PD (68*68*190).

Bedpan Washer disinfectors for the sterilization of non-invasive medical devices (Codes: MDA 0317, MDS 1004, MDS 1009; Basic UDI-DI: 5604425BPWCX):

- Plus
- Advance Automatic Door
- Advance Manual Door

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation:

N/A

Certification is based on following reports: - ES/MAD/300002232 - SUR 1.3

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: Correction of devices references in scope

