EC Certificate Full Quality Assurance System:
Certificate ES19/86765.01

The management system of

PROHS Equipamento Hospitalar e Serviços Associados S.A.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 22 April 2021 until 20 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 20 February 2008

Certification is based on reports numbered ES/MAD 228469

Multiple certificates have been issued for this scope.
The main certificate is numbered ES19/86765.00

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Digitally signed by Matei Vasile
Date: 2021.07.08 10:19:39 EEST
Reason: MoldSign Signature
Location: Moldova

PROHS Equipamento Hospitalar e Serviços Associados S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Horizontal steam sterilizer for invasive and non-invasive medical devices.

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)

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 (68*68*75)

PJ 360L (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 (68*68*190)

Bedpan Washer disinfectors:
Plus
Advance Automatic Door
Advance Manual Door

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market