EC CERTIFICATE
Full Quality Assurance System

Certificate no.: 10000379619-PA-NA-MYS Initial certification date: 25 May 2021 Valid Until: 27 May 2024

This is to certify that the management system of

Sterifast - Sterilization & Disinfection System, Lda
Parque Empresarial do Padrao No 11-5460-343 Boticas- Portugal

For design, production and final product inspection/testing of:
HYDROGEN PEROXIDE LOW TEMPERATURE STERILIZERS

has been assessed and found to comply with respect to:
the conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 25 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Veena Gunashekaran

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Notified Body 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

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Place and date: Høvik, 25 May 2021

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate History		
Revision	**Description**	**Issued Date**
0.0	Original Certificate	25 May 2021

Products covered by this Certificate:

Product Description	**Product Name**	**Class**
STERIFAST Hydrogen Peroxide Low Temperature Sterilizers	S50 1SD Ref.: STF00501SD S50 2SD Ref.: STF00502SD S110 1SD Ref.: STF01101SD S110 2SD Ref.: STF01102SD S160 2SD Ref.: STF01602SD	IIb
ECOPLASMA Hydrogen Peroxide Low Temperature Sterilizers with Low Concentration	E50 1SD Ref.: STFE0501SD E50 2SD Ref.: STFE0502SD E110 1SD Ref.: STFE1101SD E110 2SD Ref.: STFE1102SD E160 2SD Ref.: STFE1602SD	IIb

Sites covered by this certificate	
Site Name	**Site Address**
Sterifast - Sterilization & Disinfection System, Lda	Parque Empresarial do Padrao No 11-5460-343 Boticas- Portugal

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.