



**Notified Body Confirmation Letter Reference: C715725**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Sterifast - Sterilization & Disinfection Systems, LDA  
Parque Empresarial do Padrão Nº 11,  
5460-343 Boticas, Portugal  
SRN Number (if available): PT-MF-000012426

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.

Page and date:  
Rev. 004/09/15



For the issuing office:  
DNV Product Assurance AS - Notified Body 2460  
Vestveien 1, 1300 Høvik, Norway

Rajesh Kumar Chelappan  
Management Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this letter invalid.  
NOTIFIED BODY 2460: DNV Product Assurance AS, Vestveien 1, 1300 Høvik, Norway, Tel: +47 57 07 80 00, www.dnv.com



# EC CERTIFICATE

## Full Quality Assurance System

Certificate no.: 1000378910-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 Botlicas- 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:  
Havik, 25 May 2021



For the issuing office:  
DNV Product Assurance AS - Notified Body  
3469  
Veitstuveien 3, 1365 Havik, Norway

Veena Gunathakaran

Lack of fulfilment of conditions as set forth in the Certification Agreement may render this Certificate invalid.  
Notified Body 3469: DNV Product Assurance AS, Veitstuveien 3, 1365 Havik, Norway, Tel: +47 67 87 80 00, [www.dnv.com](http://www.dnv.com)