

CERTIFICATE

Number: 2153004

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Sterisets Manufacturing S.A. **Tradename: Sterisets Medical Products**

Zona Industrial I, Lote 11/14
4560-144 Guilhufe
Portugal

including the implementation meets the requirements of the standard:

ISO 13485:2016 **EN ISO 13485:2016**

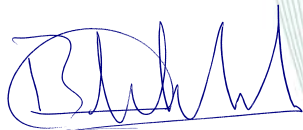
Scope:

Design, development, manufacture, storage and distribution of prefilled syringes, laminated drapes and custom procedure trays for catheterization, delivery, dialysis, disinfection, dressing, washing, wound care and surgery for patient care and general medical procedures. Including injection moulding and packaging services of non-sterile medical trays, bowls, gallipots, basins, caps and plastic instruments.

Certificate expiry date: 1 September 2027
Certificate effective date: 11 October 2024
Certified since: 8 September 2012

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed.



ADDENDUM

To certificate: 2153004

The management system of the organization(s) and/or location(s) of:

Sterisets Manufacturing S.A. **Tradenname: Sterisets Medical Products**

Zona Industrial I, Lote 11/14
4560-144 Guilhufe
Portugal

Certified organization(s) and/or locations:

Different scope

Sterisets Manufacturing S.A.
Zona Industrial 1 - Lote 34 a 35
4560-164 Guilhufe, Penafiel
Portugal

Warehousing for raw materials and components for procedure trays

Sterisets Manufacturing S.A.
Rua do Pául 88
4560-151 Guilhufe,penafiel
Portugal

Manufacture and warehousing of laminated drapes for patient care and general surgical procedures

Addendum expiry date: 1 September 2027
Addendum effective date: 11 October 2024