

# CERTIFICATE

Number: 2153004

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

## Sterisets Medical Products

Zona Industrial 1 - Lote 11 a 14  
4560-164 Guilhufe  
Penafiel  
Portugal

including the implementation meets the requirements of the standard:

# ISO 13485:2016 EN ISO 13485:2016

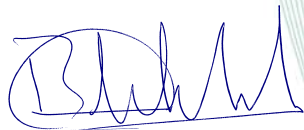
### Scope:

Design, development, manufacturing and distribution of single use medical devices and custom procedure trays, both for catheterization, disinfection, wound care, dialysis and general surgical procedures.

Certificate expiry date: 1 September 2021  
Certificate effective date: 2 November 2018  
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.A. van Vugt  
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 Medical Products

Zona Industrial 1 - Lote 11 a 14  
4560-164 Guilhufe  
Penafiel  
Portugal

Certified organization(s) and/or locations:

Different scope

Sterisets Medical Products  
Rua do Paul 88  
4560-151 Guilhufe,penafiel

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

Addendum expiry date: 1 September 2021

Addendum effective date: 2 November 2018