



CERTIFICATE

Bureau Veritas Denmark A/S certifies that the Management System of

SP Meditec A/S

Fabriksvej 17C, 3000 Helsingør, Denmark

has been audited and found to be in accordance with the requirements of the management system standards detailed below

EN ISO 13485:2016

Scope of certification:

Design, development and manufacturing of moulding, blow moulding, assembly, filling and sterile packaging of products for the medical industries. Clean room activities class 8.

This is a multi-site certificate, additional site(s) are listed on the next page(s)

Certificate number:
DK017876

Original certification date:
15-04-1997

Expiry date of Previous Cycle:
02-06-2024

Certification/Recertification audit date:

NA

Current cycle start date:
03-06-2024

Expiry date:
02-06-2027

(Subject to the continued satisfactory operation of the organisation's Management System)

Version: 3

Issue Date:
27-07-2026



Certification Body Address: Bureau Veritas Denmark A/S, Oldenborggade 25-31, 7000 Fredericia, Denmark



Further clarifications regarding the scope and validity of this certificate, and the applicability of the management system requirements, please call: (+45) 77 311 000

CERTIFICATE

SP Meditec A/S
EN ISO 13485:2016

Scope of Certification:

Site Name	Site Address	Site Scope
SP Meditec A/S	Fabriksvej 17C, 3000 Helsingør, Denmark	Design, development and manufacturing of moulding, blow moulding, assembly, filling and sterile packaging of products for the medical industries.
SP Meditec USA	782 Hwy 74 S Street, Georgia, 30269 Peachtree City, United States	Manufacturing of moulding and blow moulding, assembly, filling and sterile packaging of products for the medical industries.
SP Meditec A/S Karise	Møllevej 1, 4653 Karise, Denmark	

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