

# CERTIFICATE

Number: 2071634

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

## European Medical Contract Manufacturing B.V.

Middenkampweg 17  
6545 CH Nijmegen  
Netherlands

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

Scope:

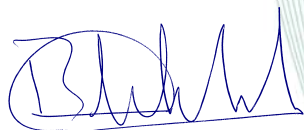
The design and development, manufacture and distribution of sterile implantable resorbable adhesion barrier devices and cement restrictors, containing tissue of animal origin, intended to be used in orthopedics, trauma surgery and wound care.

Contract manufacture of (implantable) non-active medical devices (containing tissue of animal origin) including purchasing, aseptic processing, packaging, steam sterilization, warehousing and transport.

Certificate expiry date: 1 March 2027  
Certificate effective date: 1 March 2024  
Certified since: 1 July 1995

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: 2071634

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

## European Medical Contract Manufacturing B.V.

Middenkampweg 17  
6545 CH Nijmegen  
Netherlands

Certified organization(s) and/or locations:

European Medical Contract  
Manufacturing B.V.  
Middenkampweg 17a  
6545 CH Nijmegen  
Netherlands

Different scope

The design and development, manufacture and distribution of sterile implantable resorbable adhesion barrier devices and cement restrictors, containing tissue of animal origin, intended to be used in orthopedics, trauma surgery and wound care.

Contract manufacture of (implantable) non-active medical devices (containing tissue of animal origin) including purchasing, aseptic processing, packaging, steam sterilization, warehousing and transport.

Addendum expiry date: 1 March 2027

Addendum effective date: 1 March 2024

