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 The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, development, manufacturing and delivery of sterile implantable resorbable adhesion barrier devices, acrylic bone cements and cement restrictors, containing tissue of animal origin, intended to be used in orthopedics, trauma surgery and wound care.

Contract manufacturing, including aseptic processing and packaging of (sterile) non-active medical devices.

Certificate expiry date: 1 March 2024
Certificate effective date: 1 March 2021
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.A. van Vugt 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

Certified organization(s) and/or locations:

Different scope

European Medical Contract Manufacturing Middenkampweg 17 6545 CH Nijmegen Manufacturer

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

Addendum expiry date: // March 2024 Addendum effective date: // March 2021