By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 761546 R000

Manufacturer: Mentor Medical Systems B.V.

Address:
Zernikedreef 2
Leiden
2333 CL
The Netherlands

Single Registration Number: NL-MF-000011681

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-04-16**

Current Issue Date: **2025-08-04**

Starting Validity Date: **2025-08-04**

Expiry Date: **2029-04-15**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
MENTOR™ SILTEX™ Round Gel Breast Implants Cohesive I and Cohesive II	See MDR 764223
MENTOR™ SILTEX™ Round Gel Breast Implants Cohesive I and Cohesive II, Annex XVI	See MDR 764223
MENTOR™ Smooth Round Gel Breast Implants Cohesive I	See MDR 764224
MENTOR™ Smooth Round Gel Breast Implants Cohesive I, Annex XVI	See MDR 764224
MENTOR™ CONTOUR PROFILE™ Gel Breast Implants Cohesive III (CPG™)	See MDR 764225
MENTOR™ CONTOUR PROFILE™ Gel Breast Implants Cohesive III (CPGTM), Annex XVI	See MDR 764225
MENTOR™ BECKER™ Expanders/Breast Implants	See MDR 764222
MENTOR™ BECKER™ Expanders/Breast Implants, Annex XVI	See MDR 764222

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Resterilizable Gel Breast Implant Sizers	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-04-16	3578401	Issued
Current	30425916	Amended - Removal of Cohesive II from device name MENTORTM Smooth Round Gel Breast Implants Cohesive I and Cohesive II. List devices with medical and non-medical purpose on separate lines.

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