By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 727384**

Issued To: **Mentor Medical Systems B.V.**
Zernikedreef 2
Leiden
2333 CL
The Netherlands

In respect of:

Design, development and manufacturer of: Sterile gel filled breast implants (textured and smooth), Sterile saline/gel adjustable tissue expanders and Re-sterilisable breast implant sizers.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-08** Date: **2021-02-08** Expiry Date: **2024-05-26**

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Supplementary Information to CE 727384

Issued To:

Mentor Medical Systems B.V.
Zernikedreef 2
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Number	Device Name	Intended Purpose per IFU
Class III		
MD0204	MENTOR® Round Gel Breast Implants Cohesive I and Cohesive II	See CE 727385
MD0204	MENTOR® Contour PROFILE™ Gel Breast Implants Cohesive III	See CE 727735
MD0204	MENTOR® BECKERTM Expanders/ Breast Implants Cohesive I and Cohesive II	See CE 727741
Class IIa		
MD 0106	MENTOR® Sterile Resterilizable Gel Breast Implant Sizers	Breast Implant Sizer

First Issued: **2021-02-08** Date: **2021-02-08** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 727384**
Date:	**2021-02-08**
Issued To:	**Mentor Medical Systems B.V.** **Zernikedreef 2** **Leiden** **2333 CL** **The Netherlands**

Subcontractor:	**Service(s) supplied**
Mentor 3041 Skyway Circle North Irving Texas 76051 USA	**Design** **Manufacture**
Nusil Technology 6125 West Campus Circle Drive Irving Texas 75063 USA	**Crucial Supplier**
NuSil Technology LLC 1050 Cindy Lane Carpinteria CA 93103 USA	**Crucial Supplier**

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Issued To:	**Mentor Medical Systems B.V.** **Zernikedreef 2** **Leiden** **2333 CL** **The Netherlands**

Subcontractor:	**Service(s) supplied**
SSP-SiMatrix, Inc. 1131 North US Highway 93 Victor Montana 59875 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 727384**
Date: **2021-02-08**
Issued To: **Mentor Medical Systems B.V.**
Zernikedreef 2
Leiden
2333 CL
The Netherlands

Certificate History

Date	Reference Number	Action
Current	3170310	First issue. Transfer from another Notified Body.

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