

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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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 727384

Issued To:

Mentor Medical Systems B.V.
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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

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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

List of Significant Subcontractors

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

Certificate No: **CE 727384**
Date: **2021-02-08**
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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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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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Certificate History

Certificate No: **CE 727384**
Date: **2021-02-08**
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Certificate History

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

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