

EC Certificate - Full Quality Assurance System

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

No. CE 692786
Issued To: **InMode Ltd.**
Tavor Building
Shaar Yokneam P.O. Box 533
Yokneam
2069206
Israel

In respect of:

Design and manufacture of bipolar radiofrequency (RF) applicator and accessories for the treatment of facial acne.

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: **2020-02-21**

Date: **2020-02-21**

Expiry Date: **2024-05-26**

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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 692786

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NBOG Codes	Device Name	Intended purpose per IFU
Class IIb		
MD 1104	Bipolar radiofrequency applicator	Treatment of facial acne
Class IIa		
MD 1104 MDS 7006	Applicator disposable tip (sterile)	N/A for class IIa devices

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
(BY) Medimor Ltd. Tsivonit 1 P.O Box 89 Tiberias 1410002 Israel	Manufacture
Sor-Van Radiation Ltd. Kiryat Soreq PO Box 214 Yavne 8180000 Israel	Gamma Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
Current	8936025	First issue.

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