EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 741106 R000

Manufacturer: Neoss AB

Address:
Arvid Wallgrens Backe 20
Göteborg
413 46
Sweden

Single Registration Number: SE-MF-000022321

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2024-08-21**

Current Issue Date: **2024-08-21**

Starting Validity Date: **2024-08-21**

Expiry Date: **2029-08-20**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The devices are implantable temporary non-resorbable membranes surgically placed between the soft tissue (gingiva) and the jawbone. The devices aid in the regenerative healing of bone defects in the jawbone by acting as a barrier for bacteria and soft tissue cells, and a space creator for new bone formation. The device can be placed simultaneously with dental implants. The implant can act as an additional support (either directly or indirectly) for the membrane. The devices are intended to be surgically removed when sufficient bone regeneration is achieved as judged by the treating clinician.

Risk Classification: Class IIb Implantable

Type (Codes as per (EU) 2017/2185): MDN 1103

Device Name		Model	Dimensions (mm)	Basic UDI-DI
Ti-Reinforced Membrane	NeoGen®PTFE Membrane S1	64010	29 x 14	506044033N0012MQ
	NeoGen®PTFE Membrane M1	64011	30 x 19	
	NeoGen®PTFE Membrane L1	64012	36 x 21	
	NeoGen®PTFE Membrane M	64013	32 x 22	
	NeoGen®PTFE Membrane L	64014	34 x 25	
	NeoGen®PTFE Membrane XL	64015	46 x 32	
	NeoGen® Cape PTFE Membrane	64040	28 x 22 (16 x 9)	
	NeoGen® Cape PTFE Membrane	64041	28 x 22 (22 x 9)	

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Device Name		Model	Dimensions (mm)	Basic UDI-DI
Non-Reinforced Membrane	NeoGen®PTFE Membrane	64019	18 x 12	506044033N0032MW
	NeoGen®PTFE Membrane	64020	29 x 14	
	NeoGen®PTFE Membrane	64021	34 x 25	

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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
Current	3339516	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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