By Royal Charter

EU Quality Management System Certificate

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

MDR 741100 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 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: **2022-06-17**

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

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

Expiry Date: **2027-06-16**

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable	**Intended purpose**
NeoGen® PTFE Membranes	See MDR 741106
Class IIb, Implantable, Well-established technologies	**Intended purpose**
Dental Implants and accessories	Treatment for edentulism by the replacement for one or more missing or failing teeth Treatment for jaw bone defects by ridge augmentation, ridge preservation, or grafting of peri-implant and periodontal defects

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

Device(s)	**Risk Classification**
Reusable instruments "Odontostomatology instruments"	Class Ir
Odontostomatology instruments, sterile and non-sterile	Class IIa
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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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
2022-06-17	3339432	Issued
2023-09-12	30000289	Supplemented – Addition of Dental Abutments and Dental Implants Amended – Addition of subcontractors for sterilization, manufacture and packaging of Dental Abutments and Dental Implants
2024-01-26	30074301	Amended – Class IIb, Implantable, Well-established technologies groups "Dental Implants" and "Dental Abutments" clarified as a single group "Dental Implants and accessories". Supplemented – Addition of dental membrane related devices to the group "Dental Implants and accessories". Supplemented – Addition of Class IIa device group "Odontostomatology instruments, sterile and non-sterile". Amended – Approval of critical subcontractors. Amended – Spelling correction for Class Ir group.
Current	30204192	Supplemented – Addition of NeoGen® PTFE Membranes. Amended - Approval of critical subcontractors and crucial suppliers

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