

EU Quality Management System Certificate

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

MDR 741100 R000

Manufacturer: Neoss AB

Address:

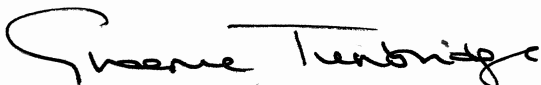
Arvid Wallgrens Backe 20
Göteborg
413 46
Sweden

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: **2025-11-17**

Starting Validity Date: **2025-11-17**

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

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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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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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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A Member of the BSI Group of Companies.

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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.
2024-08-21	30204192	Supplemented – Addition of NeoGen® PTFE Membranes. Amended - Approval of critical subcontractors and crucial suppliers
Current	30358124	Amended – Addition of suppliers for Class IIb implantable WET Dental implants and accessories and Class IIa Odontostomatology instruments.

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