By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 722819**

Issued To: **Neoss AB**
Arvid Wallgrens Backe 20
413 46 Göteborg
Sweden

In respect of:

The design and manufacture of sterile non-absorbable dental membranes, sterile dental implants, non-sterile and sterile prosthetic components and related surgical instrumentation.

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: **2020-01-23** Date: **2020-01-23** Expiry Date: **2023-09-15**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 722819**
Date: **2020-01-23**
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413 46 Göteborg
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Date	Reference Number	Action
23 January 2020	3124115	First Issue. Traceable to CE 75472.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
18 November 2022	3794150	Approval of subcontractor.

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18 November 2022

Neoss AB
Arvid Wallgrens Backe 20
413 46 Göteborg
Sweden

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 722819	93/42/EEC Annex II excluding Section 4	3794150	Approval of subcontractor.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices