EC Design-Examination Certificate

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

No. **CE 720268**

Issued To: **Medos International SARL**
Chemin Blanc 38
Le Locle
CH-2400
Switzerland

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 18:08:22 EEST
Reason: MoldSign Signature
Location: Moldova

In respect of:

CEREBASE DA Guide Sheath

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-04-13** Date: **2020-04-13** Expiry Date: **2024-05-26**

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GS9095SD	CEREBASE DA Guide Sheath	95cm	The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neuro vasculature	Class III
GS9090SD		90cm		
GS9080SD		80cm		
GS9070SD		70cm		

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Certificate History

Date	Reference Number	Action
Current	3097316	First Issue.

First Issued: **2020-04-13** Date: **2020-04-13** Expiry Date: **2024-05-26**

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Supplementary Information to CE 720268 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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Date: 28 February 2022

Changes Approved:

Date	Reference Number	Action
28 February 2022	3563245	Change in shelf life from 18 months to 26 months for the CEREBASE DA Guide Sheath.

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28 February 2022

Medos International SARL
Chemin Blanc 38
Le Locle
CH-2400
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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 720268	93/42/EEC Annex II Section 4	3563245	Change in shelf life from 18 months to 26 months for the CEREBASE DA Guide Sheath.

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,

Gary Slack
Senior Vice President, Medical Devices

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