

**Declaration of Conformity
CEREBASE DA Guide Sheath
Design Dossier DD-056-DOC, Revision 1**

Manufacturer:

Medos International SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Notified Body:

BSI
Identification Number: 2797

***Full Quality Assurance Certificate CE 552745
Design Examination Certificate CE 720268***

Products:

See Attached

Classification:

Class III, Rule 6 of Annex IX of the MDD 93/42/EEC

Start of CE Marking:

See Attached

Conformity Assessment Route:

MDD Annex II Section 3.2, including Section 4

We declare that the above-mentioned products meet the provisions of the legislation transposing
European **Medical Devices Directive 93/42/EEC**
concerning Medical Devices into the laws of the European Economic area.
All supporting documentation is available under the premises of the manufacturer.

Vivian Perez
Associate Director Regulatory Affairs
Medos International SARL

15/04/2020
DD/MM/YYYY

Nicolas Hainard
Senior Quality Operations Manager
Medos International SARL

DD/MM/YYYY

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Product Code	Description	Sterile/Non-Sterile	CE Mark Date	Classification	GMDN Code	GMDN Code Description
GS9095SD	CEREBASE DA Guide Sheath, 95cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter
GS9090SD	CEREBASE DA Guide Sheath, 90cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter
GS9080SD	CEREBASE DA Guide Sheath, 80cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter
GS9070SD	CEREBASE DA Guide Sheath, 70cm	Sterile	13-Apr-2020	Class III, Rule 6	17846	Intravascular Guiding Catheter