

ENGLISH



EU DECLARATION OF CONFORMITY

Manufacturer's Name	Cerenovus, Inc.
Manufacturer's Address	6303 Waterford District Drive Suites 215 & 315, Miami FL 33126 USA
Manufacturer's Single Registration Number (SRN)	US-MF-000025013
Authorized Representative's Name and Address	Depuy Ireland UC Loughbeg Ringaskiddy Co, Cork Ireland
Authorized Representative's Single Registration Number (SRN)	IE-AR-000009328
Notified Body Name	BSI Group The Netherlands B.V
Notified Body Identification Number	2797
Product Name	EMBOVAC Aspiration Catheter CEREGLIDE 71 Aspiration Catheter
Basic UDI-DI	EMBOVAC Aspiration Catheter 0886704a00037JV CEREGLIDE 71 Aspiration Catheter 0886704a00038JX
Product Code(s)/Product Range and Description	Refer to Attachment 1
Intended Purpose	EMBOVAC Aspiration Catheter The EMBOVAC Aspiration Catheter is intended as a conduit device for the intravascular introduction of diagnostic or interventional agents/devices in the neuro vasculature and as an aspiration device for the removal/aspiration of emboli and thrombi from selected blood vessels in the neuro vasculature. CEREGLIDE 71 Aspiration Catheter The CEREGLIDE 71 Aspiration Catheter is intended as a conduit device for the intravascular introduction of diagnostic or interventional agents/devices in the neuro vasculature and as an aspiration device for the removal/aspiration of emboli and thrombi from selected blood vessels in the neuro vasculature.
Classification	Class III (Annex VIII, Rule 6)
GMDN Code	17846
EMDN Code	C019010

ENGLISH




EU DECLARATION OF CONFORMITY

Common Specifications	Not applicable
Technical Documentation Number	MDR-TD055-CNV
<p>This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer. We Cerenovus, Inc., hereby declare this below listed Medical Devices (s) complies with Medical Device Regulation (EU) 2017/745. This declaration is made on the basis of: EU Technical Documentation Assessment Certificate Number 776941, issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745 EU Quality Systems Certificate Number MDR 776867, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.</p>	

SIGNATURE SECTION

Place of Issue	Refer to Manufacturer's Address above	
Signature	VIVIAN PEREZ Dec 21, 2023	Electronically signed by: VIVIAN PEREZ Reason: I am approving this document Date: Dec 21, 2023 13:32 EST
Name/Title	Vivian Perez Regulatory Affairs Director	
Signature	GUENTER SOLMS Dec 22, 2023	Electronically signed by: GUENTER SOLMS Reason: I am approving this document Date: Dec 22, 2023 11:07 GMT+1
Name/Title	Gunter Solms Director QA Manufacturer's Person Responsible for Regulatory Compliance	

ATTACHMENT 1

 <p>CERENOVUS <small>PART OF THE Johnson & Johnson FAMILY OF COMPANIES</small></p>	
EU DECLARATION OF CONFORMITY	
Technical Documentation Number	MDR-TD055-CNV
Manufacturer's Name	Cerenovus, Inc.

LIST OF PRODUCT CODES		
Product Name	Product Code	Product Description
EMBOVAC Aspiration Catheter	IC71125CA	EMBOVAC Aspiration Catheter 0.071 in x 125 cm
	IC71132CA	EMBOVAC Aspiration Catheter 0.071 in x 132 cm
	IC71135CA	EMBOVAC Aspiration Catheter 0.071 in x 135 cm
CEREGLIDE 71 Aspiration Catheter	NIC71115C	CEREGLIDE 71 Aspiration Catheter 0.071 in x 115 cm
	NIC71125C	CEREGLIDE 71 Aspiration Catheter 0.071 in x 125 cm
	NIC71132C	CEREGLIDE 71 Aspiration Catheter 0.071 in x 132 cm
	NIC71137C	CEREGLIDE 71 Aspiration Catheter 0.071 in x 137 cm