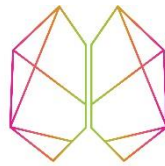


English



CERENOVUS

PART OF THE  FAMILY OF COMPANIES

EU DECLARATION OF CONFORMITY

Manufacturer's Name	Cerenovus, Inc.
Manufacturer's Address	6303 Waterford District Drive Suites 215 & 315, Miami, Florida 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	British Standards Institution (BSI) Netherlands
Notified Body Identification Number	2797
Technical Documentation Number	MDR-TD036-CNV
Product and Trade Name(s)	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device
Product Code(s)/Product Range and Description	Refer to Attachment 1
Intended Purpose	The CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device is intended to be employed as a scaffold for coils used for intracranial aneurysm occlusion
Classification	Class III (Annex VIII, Rule 8)
GMDN Code	46352
EMDN Code	P0799
Basic UDI-DI value	0886704a00025JN

This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

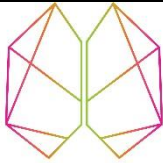
We, Cerenovus, Inc., hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of: EU Technical Documentation Assessment Certificate Number MDR 776943 issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745.

EU Quality System 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.

SIGNATURE SECTION			
Place of Issue	Refer to Manufacturer's Address above		
Signature	<i>VIVIAN PEREZ</i> Electronically signed by: VIVIAN PEREZ Reason: I am approving this document Date: May 13, 2024 10:15 EDT	Date	May 13, 2024
Name/Title	Vivian Perez, Regulatory Affairs Director		
Signature	<i>GUENTER SOLMS</i> Electronically signed by: GUENTER SOLMS Reason: I am approving this document Date: May 13, 2024 10:47 EDT	Date	May 13, 2024
Name/Title	Gunter Solms, Sr Director QA		
	Manufacturer's Person Responsible for Regulatory Compliance		

ATTACHMENT 1

 CERENOVUS <small>PART OF THE <i>Johnson & Johnson</i> FAMILY OF COMPANIES</small>	
EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Cerenovus, Inc.
Technical Documentation Number	MDR-TD036-CNV

LIST OF PRODUCT CODES/PRODUCTS RANGE

Product and Trade Names(s)	Product Code	Product Description
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC401612	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 16mm
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC402312	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 23mm
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC403012	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 30mm
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC403912	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 39mm
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC401600	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 16mm no distal tip
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC402300	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 23mm no distal tip
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC403000	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 30mm no distal tip
CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device	ENC403900	CERENOVUS ENTERPRISE 2 Vascular Reconstruction Device 4.0mm X 39mm no distal tip