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Name: EMBOTRAP Product Family MDR Declaration of Conformity

Windchill Signature History Report			
Signature	Role	Event Date	Vote
Jha, Abhishek [DPYUS NON-J&J] (AJha22)	Document Management	07-Oct-2022 04:38:03 EDT	Approve
Cusack, Helen [DPYIE] (hcusack)	Quality Engineering	06-Oct-2022 15:44:59 EDT	Approve

Title: EMBOTRAP Product Family EU MDR Declaration of Conformity	
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English	
EMBOTRAP Product Family	
EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Neuravi Limited
Manufacturer's Address	Neuravi Limited, Block 3, Ballybrit Business Park, Galway, Ireland
Manufacturer's Single Registration Number (SRN)	IE-MF-000007612
Notified Body Name	BSI Group The Netherlands B.V.
Notified Body Identification Number	2797
Technical Documentation Number	500602981
Product and Trade Name(s)	EMBOTRAP III Revascularization Device
Product Code(s)/Product Range and Description	ET307522 ET307537 ET307645
Intended Purpose	The EMBOTRAP™ III Revascularization Device (the Device) is intended to be used to restore blood flow in patients experiencing an acute ischemic stroke due to a large vessel neurovascular occlusion. The Device is designed for use in the anterior and posterior neurovasculature in vessels, such as the internal carotid artery, the M1 and M2 segments of the middle cerebral artery, the A1 and A2 segments of the anterior cerebral artery, the basilar, the posterior cerebral and the vertebral arteries.
Classification	Class III (Annex VIII, Chapter III, Rule 6)
GMDN Code	58173
EMDN Code	C019010
Basic UDI-DI value	0886704a00015JK
Common Specifications	N/A – Neuravi will comply with applicable Common Specifications as they become available.
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.	
We, Neuravi, hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.	

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<p>English</p> <p>EMBOTRAP Product Family</p> <p>EU DECLARATION OF CONFORMITY</p>
<p>This declaration is made on the basis of: EU Technical Documentation Assessment Certificate Number MDR 726531, 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 726529, 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		Date	Refer to date from electronic signature
Name/Title	Niall Fox Director of Regulatory Affairs		
Signature		Date	Refer to date from electronic signature
Name/Title	Helen Cusack Head of Quality		
	Manufacturer's Person Responsible for Regulatory Compliance		