

ENGLISH



# medos international

## EU DECLARATION OF CONFORMITY

<b>Manufacturer's Name</b>	Medos International SARL
<b>Manufacturer's Address</b>	Chemin Blanc 38 Le Locle CH-2400 Switzerland
<b>Manufacturer's Single Registration Number (SRN)</b>	CH-MF-000014268
<b>Authorized Representative's Name and Address</b>	DePuy Ireland UC Loughbeg Ringaskiddy Co. Cork Ireland
<b>Authorized Representative's Single Registration Number (SRN)</b>	IE-AR-000009328
<b>Notified Body Name</b>	British Standards Institution (BSI) Netherlands
<b>Notified Body Identification Number</b>	2797
<b>Product Name</b>	Cerenovus Microcatheters: PROWLER 10 PROWLER 14 PROWLER PLUS PROWLER SELECT LP-ES PROWLER SELECT PLUS RAPIDTRANSIT
<b>Basic UDI-DI</b>	0886704a00003JC
<b>Product Code(s)/Product Range and Description</b>	Refer to Attachment 1
<b>Intended Purpose</b>	The Cerenovus Microcatheter is intended as a conduit for endovascular use during diagnostic and/or interventional procedures in the peripheral and neuro vasculature.
<b>Classification</b>	Class III (Annex VIII, Chapter III, Rule 6)
<b>GMDN Code</b>	10691
<b>EMDN Code</b>	C010499

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### EU DECLARATION OF CONFORMITY

<b>Technical Documentation Number</b>	MDR-TD033
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**This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.**

We, Medos International SARL, 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 756263 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 724423 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

<b>Place of Issue</b>	Refer to Manufacturer's Address above
<b>Signature/Date</b>	
<b>Name/Title</b>	Vivian Perez Regulatory Affairs Associate Director
<b>Signature/Date</b>	
<b>Name/Title</b>	Nicolas Hainard Director QA, Medos International SARL
	<b>Manufacturer's Person Responsible for Regulatory Compliance</b>

**ATTACHMENT 1**

<b>ENGLISH</b>	
 <b>medos international</b>	
<b>EU DECLARATION OF CONFORMITY</b>	
<b>Technical Documentation Number</b>	MDR-TD033
<b>Manufacturer's Name</b>	Medos International SARL

<b>ProductName</b>	<b>Product Code</b>	<b>Product Description</b>
RAPIDTRANSIT Microcatheter	601-210	70cm w/ext (Usable Length), 30cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
RAPIDTRANSIT Microcatheter	601-220	85cm w/ext. (Usable Length), 30cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
RAPIDTRANSIT Microcatheter	601-251	150cm w/ext. (Usable Length), 50cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
RAPIDTRANSIT Microcatheter	601-251X	150cm (Usable Length), 50cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Band, Straight Tip Shape
RAPIDTRANSIT Microcatheter	601-271	170cm w/ext. (Usable Length), 50cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER 10 Microcatheter	606-051	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.7F (Outer Diameter), 0.015" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER 10 Microcatheter	606-051X	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.7F (Outer Diameter), 0.015" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER 14 Microcatheter	606-151	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER 14 Microcatheter	606-151X	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER 14 Microcatheter	606-171	170cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER PLUS Microcatheter	606-2510	150cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape

ProductName	Product Code	Product Description
PROWLER PLUS Microcatheter	606-2511	150cm (Usable Length), 45cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter) 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER PLUS Microcatheter	606-2510X	150cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER PLUS Microcatheter	606-2511X	150cm (Usable Length), 45cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER PLUS Microcatheter	606-2310	135cm (Usable Length), 20cm (Distal Flexible Length) 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER PLUS Microcatheter	606-2910	110cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER 10 Microcatheter	606-051FX	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.7F (Outer Diameter), 0.015" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER 10 Microcatheter	606-051JX	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.7F (Outer Diameter), 0.015" (Inner Diameter), 2 Marker Bands, J Tip Shape
PROWLER 10 Microcatheter	606-051MX	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.7F (Outer Diameter), 0.015" (Inner Diameter), 2 Marker Bands, 90° Tip Shape
PROWLER 14 Microcatheter	606-151FX	150cm (Usable Length), 50cm (Distal Flexible Length) 2.3F/1.9F (Outer Diameter) 0.0165" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER 14 Microcatheter	606-151JX	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, J Tip Shape
PROWLER 14 Microcatheter	606-151MX	150cm (Usable Length), 50cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, 90° Tip Shape
PROWLER PLUS Microcatheter	606-2510FX	150cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER PLUS Microcatheter	606-2510JX	150cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, J Tip Shape
PROWLER PLUS Microcatheter	606-2510MX	150cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, 90° Tip Shape
PROWLER PLUS Microcatheter	606-2511FX	150cm (Usable Length), 45cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER PLUS Microcatheter	606-2310J	135cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, J Tip Shape

<b>ProductName</b>	<b>Product Code</b>	<b>Product Description</b>
PROWLER PLUS Microcatheter	606-2310F	135cm (Usable Length), 20cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter); 1 Marker Band, 45° Tip Shape
PROWLER SELECT LP-ES Microcatheter	606-S155X	150cm (Usable Length), 5cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER SELECT LP-ES Microcatheter	606-S155MX	150cm (Usable Length), 5cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, 90° Tip Shape
PROWLER SELECT LP-ES Microcatheter	606-S155FX	150cm (Usable Length), 5cm (Distal Flexible Length), 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER SELECT LP-ES Microcatheter	606-S155JX	150cm (Usable Length), 5cm (Distal Flexible Length) 2.3F/1.9F (Outer Diameter), 0.0165" (Inner Diameter), 2 Marker Bands, J Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S252	150cm (Usable Length), 15cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 1 Marker Band, Straight Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S252X	150cm (Usable Length), 15cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S252FX	150cm (Usable Length), 15cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S255X	150cm (Usable Length), 5cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S255MX	150cm (Usable Length), 5cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, 90° Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S255FX	150cm (Usable Length), 5cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, 45° Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S255JX	150cm (Usable Length), 5cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, J Tip Shape
PROWLER SELECT PLUS Microcatheter	606-S272X	170cm (Usable Length), 15cm (Distal Flexible Length), 2.8F/2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, Straight Tip Shape
PROWLER SELECT PLUS Microcatheter	MC21160C2	160cm (Usable Length), 5cm (Distal Flexible Length), 2.8F / 2.3F (Outer Diameter), 0.021" (Inner Diameter), 2 Marker Bands, Straight Tip Shape