

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 756263 R000

Manufacturer: Medos International SARL

Address:

Chemin Blanc 38
Le Locle
CH-2400
Switzerland

Single Registration Number: CH-MF-000014268

EU Authorised Representative: DePuy Ireland UC

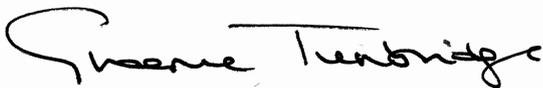
Address:

Loughbeg
Ringaskiddy
Co. Cork
Ireland

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-17**

Date: **2022-03-17**

Expiry Date: **2027-03-16**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The Cerenovus Microcatheter is intended as a conduit for endovascular use during diagnostic and/or interventional procedures in the peripheral and neuro vasculature.

Risk Classification: Class III

Basic UDI-DI: 0886704a00003JC

Type (per EU 2017/2185): MDN 1203

Device Name	Model	Additional Information (optional, ex. dimensions or other critical device parameters)
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

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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
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

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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
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

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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



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3507547	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.