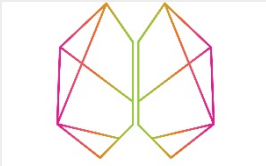
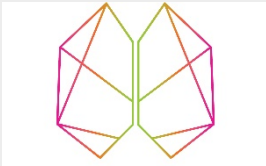



| ENGLISH  CERENOVUS <small>PART OF THE Johnson & Johnson FAMILY OF COMPANIES</small> EU DECLARATION OF CONFORMITY | |
|---|--|
| Manufacturer's Name | Cerenovus, Inc. |
| Manufacturer's Address | 6303 Waterford District Drive Suites 215 & 315, Miami FL 33126 USA |
| Manufacturers Single Registration Number (SRN) | US-MF-000025013 |
| Authorized Representatives 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 | ENVOY Guiding Catheter |
| Basic UDI-DI | 0886704a00027JS |
| Product Code(s)/Product Range and Description | Refer to Attachment 1 |
| Intended Purpose | The ENVOY Guiding Catheter is intended as a conduit device for the intravascular introduction of interventional/diagnostic devices to the neuro vasculature. |
| Classification | Class III (Annex VIII, Rule 6) |
| GMDN Code | 17846 |
| EMDN Code | C010499 |

| | |
|--|---------------|
| <p>ENGLISH</p>  <p>CERENOVUS <small>PART OF THE Johnson & Johnson FAMILY OF COMPANIES</small></p> <p>EU DECLARATION OF CONFORMITY</p> | |
| Technical Documentation Number | MDR-TD031-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 776937, 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 | <p>Signature: <i>Samuel Shimp</i> <small>Electronically signed by: Samuel Shimp Reason: I am approving this document Date: Oct 26, 2023 18:11 EDT</small></p> <p>Email: sshimp@its.jnj.com</p> <p style="text-align: right; font-size: 1.2em;">Oct 26, 2023</p> |
| Name/Title | Samuel Shimp Regulatory Affairs Associate Director |
| Signature | <p>Signature: <i>GUENTER SOLMS</i> <small>Electronically signed by: GUENTER SOLMS Reason: I am approving this document Date: Oct 30, 2023 17:49 EDT</small></p> <p>Email: gsolms2@its.jnj.com</p> <p style="text-align: right; font-size: 1.2em;">Oct 30, 2023</p> |
| Name/Title | Gunter Solms Director QA |
| | Manufacturer's Person Responsible for Regulatory Compliance |

ATTACHMENT 1

| | |
|---|-----------------|
|  CERENOVUS <small>PART OF THE Johnson & Johnson FAMILY OF COMPANIES</small> | |
| EU DECLARATION OF CONFORMITY | |
| Technical Documentation Number | MDR-TD031-CNV |
| Manufacturer's Name | Cerenovus, Inc. |

| Product Name | Product Code | Product Description |
|------------------------|--------------|----------------------------------|
| ENVOY Guiding Catheter | 77826090 | ENVOY, 7F, 90 cm, Straight |
| | 77826000 | ENVOY, 7F, 100 cm, Straight |
| | 77825690 | ENVOY, 7F, 90 cm, MPC |
| | 77825600 | ENVOY, 7F, 100 cm, MPC |
| | 77825890 | ENVOY, 7F, 90 cm, MPD |
| | 77825800 | ENVOY, 7F, 100 cm, MPD |
| | 77824890 | ENVOY, 7F, 90 cm, CBL |
| | 77824800 | ENVOY, 7F, 100 cm, CBL |
| | 77825490 | ENVOY, 7F, 90 cm, H1 |
| | 77825400 | ENVOY, 7F, 100 cm, H1 |
| | 77825290 | ENVOY, 7F, 90cm, Simmons 2 |
| | 77825200 | ENVOY, 7F, 100cm, Simmons 2 |
| | 77826090B | ENVOY, 7F, 90 cm, Straight, XB |
| | 77826000B | ENVOY, 7F, 100 cm, Straight, XB |
| | 77825690B | ENVOY, 7F, 90 cm, MPC, XB |
| | 77825600B | ENVOY, 7F, 100 cm, MPC, XB |
| | 77825890B | ENVOY, 7F, 90 cm, MPD, XB |
| | 77825800B | ENVOY, 7F, 100 cm, MPD, XB |
| | 77824890B | ENVOY, 7F, 90 cm, CBL, XB |
| | 77824800B | ENVOY, 7F, 100 cm, CBL, XB |
| | 77825490B | ENVOY, 7F, 90 cm, H1, XB |
| | 77825400B | ENVOY, 7F, 100 cm, H1, XB |
| | 77825290B | ENVOY, 7F, 90cm, Simmons 2, XB |
| | 77825200B | ENVOY, 7Fr, 100cm, Simmons 2, XB |
| | 67026090B | ENVOY, 6F, 90 cm, Straight, XB |
| | 67026000B | ENVOY, 6F, 100 cm, Straight, XB |

| Product Name | Product Code | Product Description |
|--------------|--------------|----------------------------------|
| | 67025690B | ENVOY, 6F, 90 cm, MPC, XB |
| | 67025600B | ENVOY, 6F, 100 cm, MPC, XB |
| | 67025890B | ENVOY, 6F, 90 cm, MPD, XB |
| | 67025800B | ENVOY, 6F, 100 cm, MPD, XB |
| | 67025090B | ENVOY, 6F, 90 cm, CBL, XB |
| | 67025000B | ENVOY, 6F, 100 cm, CBL, XB |
| | 67025490B | ENVOY, 6F, 90 cm, H1, XB |
| | 67025400B | ENVOY, 6F, 100 cm, H1, XB |
| | 67025290B | ENVOY, 6F, 90 cm, Simmons 2, XB |
| | 67025200B | ENVOY, 6F, 100 cm, Simmons 2, XB |
| | 67026090 | ENVOY, 6F, 90 cm, Straight |
| | 67026000 | ENVOY, 6F, 100 cm, Straight |
| | 67025690 | ENVOY, 6F, 90 cm, MPC |
| | 67025600 | ENVOY, 6F, 100 cm, MPC |
| | 67025890 | ENVOY, 6F, 90 cm, MPD |
| | 67025800 | ENVOY, 6F, 100 cm, MPD |
| | 67025090 | ENVOY, 6F, 90 cm, CBL |
| | 67025000 | ENVOY, 6F, 100 cm, CBL |
| | 67025490 | ENVOY, 6F, 90 cm, H1 |
| | 67025400 | ENVOY, 6F, 100 cm, H1 |
| | 67025290 | ENVOY, 6F, 90 cm, Simmons 2 |
| | 67025200 | ENVOY, 6F, 100 cm, Simmons 2 |
| | 55626090 | ENVOY, 5F, 90 cm, Straight |
| | 55626000 | ENVOY, 5F, 100 cm, Straight |
| | 55625690 | ENVOY, 5F, 90 cm, MPC |
| | 55625600 | ENVOY, 5F, 100 cm, MPC |
| | 55625890 | ENVOY, 5F, 90 cm, MPD |
| | 55625800 | ENVOY, 5F, 100 cm, MPD |
| | 55625090 | ENVOY, 5F, 90 cm, CBL |
| | 55625000 | ENVOY, 5F, 100 cm, CBL |
| | 55625490 | ENVOY, 5F, 90 cm, H1 |
| | 55625400 | ENVOY, 5F, 100 cm, H1 |