Q'apel
MEDICAL, INC.

## EC DECLARATION OF CONFORMITY

**EC Declaration of Conformity Annex IX, Chapter II to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017**

**Manufacturer:** **Q'Apel Medical, Inc.**
**Manufacturer's Address** **46708 Lakeview Blvd, Fremont, CA 94538**

**Device/s:**

**Description: Walrus 087 Balloon Guide Catheter**
**Manufacturer's SRN: US-MF-000022759**
**Basic UDI-DI: 0857545008NEUROACCESKD**

**Conformity Route:**
**EU Product Risk Class: Class III, Rule 6 (3rd Indent) per MDR 2017/745, Annex VIII**
Identification of Certificate Issued: G70 111186 0002
**Quality Management System: Annex IX, Chapters I and III**
Identification of Certificate Issued: G12 111186 0001

### Declaration of Conformity

Q'Apel Medical, Inc. has sole responsibility and declares that the Walrus 087 Balloon Guide Catheter listed on the attached Device Schedule conforms to the relevant provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 *(Medical Device Regulation-MDR)* and is in accordance with ISO 13485:2016 Quality management Systems as implemented by the European Union's Medical Devices Regulations and verified by Q'Apel Medical, Inc.'s Notified Body.

Q'Apel Medical, Inc. confirms that no other application has been lodged with another Notified Body for the same device related Quality Management System.

Q'Apel Medical, Inc. agrees to develop, implement, and maintain a formally recognized Quality Management System to ensure continued adequacy and efficacy.

Q'Apel Medical, Inc. agrees to develop, implement, and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Q'Apel Medical, Inc. confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Q'Apel Medical, Inc. agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Q'Apel Medical, Inc. **appointed Notified Body is**:

TUV SUD Product Services GmbH (Certification Body)
Ridlerstrabe 65
80339 Munchen, Germany
Notified Body Identification Number: 0123

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.15 16:26:58 EEST
Reason: MoldSign Signature
Location: Moldova

Q'apel
MEDICAL, INC.

Q'Apel Medical, Inc. appointed **Authorized Representative is**:

MedEnvoy Global BV,
Prinses Margrietplantsoen 33 – Suite 123, 2595 AM
The Hague, The Netherlands
Authorized Representative SRN: NL-AR-000024028

Signed by the Q'Apel Medical, Inc. designated representative:

Name: Jim Talbot Title: V.P. Regulatory Affairs, Clinical, and Quality Date: 2023-03-31

Signature: Jim Talbot

Device Schedule

| Product or Trade Name | Product Code | Catalogue Number | Intended Purpose/ Indications for Use | Basic UDI-DI |
|---|---|---|---|---|
| Walrus 087 Balloon Guide Catheter System | MDN 1203<br><br>EMDN C0104020103 | BG8087-090<br>BG8087-095<br>BG8087-100 | The 087 Balloon Guide Catheter System is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovasculature. The balloon provides temporary vascular occlusion during such procedures. The 087 Balloon Guide Catheter system is also indicated for use as a conduit for Retrieval devices. | 0857545008NEUROACCESKD |

This declaration of conformity is issued under the sole responsibility of Q'Apel Medical, Inc.
We hereby declare that the product identified above is in conformity with all relevant provisions of (EU) MDR 2017/745 for medical devices. This Declaration of Conformity is made under Annex IX of this regulation and is in conformity with the following standards:

ISO 80369-7:2017
ASTM D 4169-16
ASTM F1980-16
ASTM D 4332-14
ASTM F88/F88M: 2015
ASTM F2096-11:2019
ISO 20417: 2021
EN 556-1: 2001, AC: 2006

Q'apel
MEDICAL, INC.

EN 1041:2008/A1:2013
ISO 10555-1: 2013/ AMD 1:2017
ISO 10555-4:2013
ISO 11135:2014
ISO 11138-1: 2017
ISO 11607-1: 2020
ISO 11607-2: 2020
ISO 11737-1:2018
ISO 15223-1: 2012
ISO 10993-1: 2020
ISO 10993-4:2017
ISO 10993-5:2009
ISO 10993-7: 2009
ISO 10993-10:2013
ISO 10993-11: 2018
EN ISO 11737:2018
AAMI TIR42:2021
AAMI TIR 28:2016
United States Pharmacopeia 31 and National Formulary 26 <USP 788>
ASTM F640-20
ASTMF756-17
ASTM F619-20
ASTM F2382-18
United States Pharmacopeia 41, National Formulary 36, 2018. <1184> Sensitization Testing
United States Pharmacopeia 41, National Formulary 36, 2018. <151> Pyrogen Test
ANSI/AAMI ST72: 2019
DIN EN 13868:2002
ISO 13485: 2016
ISO 14971:2019
ISO 15223-1:2021
ISO 14155:2020
EN ISO 14644-1:2015
EN ISO 14698-1:2003
EN 13868:2002