Bonree Medical Co., Ltd.
Add: 1st floor of Building No.2, Building No.4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, China.
Tel: +86 760 8520 7588 Fax: +86 760 8520 7568
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Declaration for the Compliance with the Criteria Set Out in REGULATION (EU) 2023/607 For the Extension of the Validity of CE Certificate

Bonree Medical Co., Ltd.

1st floor of Building No.2 Building No.4, Longzhu Village Economic Estate Longzhu Avenue, Nanlang 528451, Zhongshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA.

SRN:CN-MF-000017844

The CE Certificate, G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00 / G2S 094928 0002 Rev. 01 & GCQ 094928 0009 Rev. 00, issued by TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany. EC certificate(s) valid until:2024-05-26.

The risk class of the device, Rectal Catheters is Class I respectively according to Regulation (EU)2017/745. The risk class of the device, Intubating Stylets and Stomach Tubes is Class IIa respectively according to Regulation (EU)2017/745.

Therefore, validity of certificate G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00 / G2S 094928 0002 Rev. 01 & GCQ 094928 0009 Rev. 00 is extended through 31st December 2028, according to Regulation (EU) 2023/607. A full list of devices that will be benefiting from the extension of the Validity of CE Certificate can be located in Appendix A of this document.

The Notified Body, TÜV SÜD Product Service GmbH, that issued the CE Certificate, G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00 / G2S 094928 0002 Rev. 01 & GCQ 094928 0009 Rev. 00, will remain responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices that it has certified.

Bonree Medical Co., Ltd declares that the following criteria set out in REGULATION (EU)2023/607 are met to make them eligible for the extension of the validity of the CE Certificate;

- √ QMS is in place in accordance with Article 10(9)MDR since 21 June 2023
- √ TUV SÜD Product Service GmbH is Notified Body with identification no. 0123
- √ There are no significant changes in the design
- √ There is no change in the intended use of the devices
- √ The devices do not present an unacceptable risk.
- √ The devices continue to comply with Directive 93/42/EEC MDD,as applicable.
- √ The MDR requirements relating to post-market surveillance,market surveillance,vigilance, registration of economic operators and of devices are met.
- √ Notified Body responsible for the surveillance of the devices.

Name: **Ariel Lee** Position: Sales Manager

Place: GUANGZHOU,CHINA Date: 08/28/2024 Signature: Ariel

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Appendix A-List of Devices Benefiting from Extension of the Validity of CE Certificates

Product Details,Names or Trade Names	Certificate No.	Classification
Rectal Catheters	G2S 094928 0002 Rev. 01& GCQ 094928 0009 Rev. 00	Ⅰ Sterile (Rule 5, Annex IX, MDD 93/42/EEC)
Intubating Stylets	G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00	IIa (Rule 5, Annex IX, MDD 93/42/EEC)
Stomach Tubes	G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00	IIa (Rule 5, Annex IX, MDD 93/42/EEC)
Feeding Tubes	G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00	IIa (Rule 5, Annex IX, MDD 93/42/EEC)
Oxygen Masks	G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00	IIa (Rule 5, Annex IX, MDD 93/42/EEC)
Oxygen Tubings	G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00	IIa (Rule 5, Annex IX, MDD 93/42/EEC)

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SELF DECLARATION

We, Bonree Medical Co., Ltd, confirm that, our existing MDD Certificate (No.:G2 094928 0004 Rev. 03 & GCQ 094928 0008 Rev. 00 / G2S 094928 0002 Rev. 01& GCQ 094928 0009 Rev. 00) which expires on 2024-05-26, will benefit from the MDR transition period until 31 December 2028, taking into consideration the framework of Regulation EU 2023/607 amending Regulations (EU)2017/745 as regards the transitional provisions for certain medical devices. The required contract for MDR conformity assessment has already been signed by our Notified Body, TÜV SÜD Product Service GmbH.

We confirm that all the products that are listed in the above mentioned certificate will benefit from this transition.

Authorized Signature:

Date: 08/28/2024