

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 799116 R000

Manufacturer: Nanjing Orange Medical Product Co., Ltd.

Address:

Building 8, No. 9 Caofang Road
Longchi Street
Luhe District
Nanjing City
Jiangsu
210044
China

Single Registration Number: CN-MF-000039246

EU Authorised Representative: SUNGO Europe B.V.

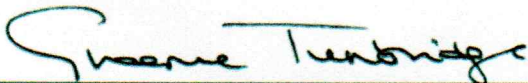
Address:

Fascinatio Boulevard 522
Unit 1.7
2909VA Capelle aan den IJssel
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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 Global Regulatory & Quality

First Issue Date: **2024-06-25**

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