EC Declaration of Conformity

Manufacturer:

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We, the manufacturer, herewith declare that the products

Products: Hand Rehabilitation Device

Model Ref: SL-FR01、SL-FR01S、SL-FR02、SL-FR02S、SL-FR02MS、SL-FR03

GMDN CODE: 34200

meet the provisions of Regulation (EU) 2017/745, MDR.

The medical device has been assigned to Class I according to Annex VIII, Regulation (EU) 2017/745, MDR. It bears the mark

CE

The product concerned has been designed and manufactured under a quality management system according to Annex IX of **Regulation (EU) 2017/745**.

Compliance of the designated product with the **Regulation (EU) 2017/745** and following the procedure relating to the EC Declaration of Conformity set out in Annex IX of Regulation (EU) 2017/745 and in conformity to the following standards or other normative documents:

EN ISO 13485:2016, **EN ISO 14971:2019,** **EN 1041:2016,** **EN ISO 15223-1:2016,** **EN ISO 780:2015**	**EN60601-1-2:2015,** **EN IEC 61000-3-2:2019,** **EN IEC 61000-3-3:2013+A1:2019**	**MEDDEV 2.7/1 Rev.4**	**EN ISO 10933-1:2018,** **EN ISO 10993-5:2009,** **EN ISO 10993-10:2013**

The above mentioned declaration of conformity is exclusively under the sole responsibility of manufacturer: **Xiamen Weiyou Intelligent Technology Co., Ltd.**

Xiamen/ Oct 11, 2022
Place, date

Kelly Guo General Manager
Legally binding signature, Function