Subject: Declaration of transition to Regulation (EC) 2017/745 for the medical device Sinaqua

Following the publication in the Official Journal of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745, published on 20/03/2023, as regards transitional arrangements for certain medical devices, Welcare Industries Spa, with registered office in Via San Giovanni sul Muro 18, Milano, 20121 and production site in via dei falegnami 07 Orvieto (TR) 05018, under its sole responsibility

DECLARES

- **the medical device in question falls under the definition of medical device pursuant to Article 2 of EU Reg. 2017/745 (EU MDR) and is therefore intended for certification under said Regulation;**
- **the subject medical device remains in compliance with Directive 93/42/EC. This device has not undergone significant changes in design and intended use;**
- **the subject medical device does not pose a risk to the health and safety of patients, users or other persons or to public health;**
- **Welcare Industries SpA wishes to take advantage of the extended period of validity of certificate No. 0477/MDD.20/3778 issued by the No. 0477;**
- **Welcare Industries SpA have signed an agreement on 08 April 2022 with accredited notified body no. 0477 in accordance with section 4.3, second paragraph, of Annex VII of the EU MDR for conformity assessment of the device in question. These devices fulfil the conditions of Article 120, paragraph 2, sub-section 2, points (a) or (b) and paragraph 3c.;**
- **Welcare Industries SpA has adapted its quality management system (QMS) in accordance with Article 10(9) of the MDR;**
- **The submission of the technical dossier to the accredited Notified Body No. 0477 for conformity assessment to the EU MDR was made on July 2022;**

Below the email from the regulatory office for clarification:
regulatory@welcaremedical.com

Date and place

13th April 2023, Orvieto

Firma

CEO

Fulvia Lazzarotto

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