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EU Declaration of Conformity

Manufacturer: *AMPall Co., Ltd.*

European representative: *AR Experts B.V.*

Amerlandseweg 7, 3621 ZC Breukelen, The Netherlands

Tel: +31 (0)88 995 1333 E-mail: info@ar-experts.eu

Product: *Syringe Pump*

Model: *SP-8800*

Classification: *Class IIb by Rule 11 of Annex IX, MDD93/42/EEC amended by MDD2007/47/EC*

Conformity Assessment Route: *Annex II, Excluding Section 4, MDD93/42/EEC amended by MDD2007/47/EC*

Applicable Normative References:

EN ISO 13485:2016, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010/A1:2015, EN 62304: 2006, EN 62366:2008, EN ISO 15223-1:2016, EN 1041:2008, EN 60601-2-24:2015

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

SP-8800 is manufactured in compliance with the provisions of RoHS 2 DIRECTIVE 2011/65/EU and ROHS 3 (EU) 2015/863.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Notified Body: *SGS Belgium NV (Notified Body 1639)*

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EC certificate: *KR19/81826211*

Start of CE-marking: *2007. 07. 12*

Place, Date of issue: *Seoul, Korea, 2023.10.10*

Signature:

President

10 Oct. 2023

on behalf of AMPall Co.,Ltd.