



AMPall CO., LTD.

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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
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Product: Infusion pump

Model: IP-7700

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.

IP-7700 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.