EC Certificate Full Quality Assurance System: Certificate KR19/81826211

The management system of

AMPall Co., Ltd.

3F, Annex Hankook Junja Hyeopdong B/D (Gasan-Dong),
114, Gasan digital 2-ro, Geumcheon-gu, 08506 Seoul, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Infusion pump (Model: IP-7700);
Syringe pump (Model: SP-8800);
Blood Pressure Monitor (Model: BP 868F);
PCA pump (Model: PP-9900), Sterile single use Infusion set (PP-9900ACB series);
Sterile single use PCA pump (Model: PP-9800B1, PP-9800B2, PP-9800C1, PP-9800C2);
X-ray Bone Densitometer (Brand: Osteo Checker, Model: pDEXA-kico).

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 12 July 2007
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL Y-PC/07167

Authorised by

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02