EC Certificate Full Quality Assurance System: Certificate KR07/00886

The management system of

AMPall Co., Ltd.

3F, Annex HanKook Junja HyeopDong B/D 371-51, Gasan-Dong,
Geumcheon-Gu, 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) and 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 9 September 2016 until 12 July 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 4 June 2019
Issue 9. Certified since 12 July 2007

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

Authorised by

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