

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

SGS United Kingdom Ltd, Notified Body 0120 2028 Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be nonsecuted to the fullest extent of the law