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

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

AMPall Co., Ltd.
Annex 3F, Hankook Junja Hyeopdong B/D
114 Gasan digital 2-ro, Geumcheon-gu
Seoul, 08506
Republic of Korea
SRN: KR-MF-000010967

Jun 26, 2024

Confirmation Letter Reference: CLNB1639 - KR/SEL/Y-PC/07167

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

Manufacturer
AMPall Co., Ltd.
Annex 3F, Hankook Junja Hyeopdong B/D
114 Gasan digital 2-ro, Geumcheon-gu
Seoul, 08506
Republic of Korea
SRN: KR-MF-000010967

Authorized representative
AR Experts B.V.
Amerlandseweg, 7
3621ZC Breukelen
Netherlands
SRN: NL-AR-000023989

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate

surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

pp [Haldun OGUZ]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Blood Pressure Monitor (Model: BP 868F) Basic UDI-DI: 92820AMP-BP-Monitor8C	Class IIa	N/A	N/A	NB1639 KR19/81826211
PCA pump (Model: PP-9900) Basic UDI-DI: 92820AMP-PCA-PumpSG	Class IIb	N/A	N/A	NB1639 KR19/81826211
Sterile single-use Infusion set (PP-9900ACB series) Basic UDI-DI: 92820AMP-Infusion-SetVR	Class IIb	N/A	N/A	NB1639 KR19/81826211
Infusion pump (Model: IP-7700) Basic UDI-DI: 92820AMP-Infusion_PumpRZ	Class IIb	N/A	N/A	NB1639 KR19/81826211
Syringe pump (Model: SP-8800) Basic UDI-DI: 92820AMP-Syringe_PumpMV	Class IIb	N/A	N/A	NB1639 KR19/81826211

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
N/A - All device are covered by NB1639 surveillance audit	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/26	Version 1	Initial issue