Ace Medical Co., Ltd.
(Factory) 33, Naeyu-gil 124beon-gil, Deogyang-gu, Goyang-si, Gyeonggi-do, 10264, Republic of Korea
(HO & R&D center) 30, Godeokbizvalley-ro 4-gil, Gangdong-gu, Seoul, 05203, Republic of Korea
SRN: KR-MF-000022760

Jun 11, 2024

Confirmation Letter Reference: CLNB1639 - WW/PCI/201592

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
Ace Medical Co., Ltd.
(Factory) 33, Naeyu-gil 124beon-gil, Deogyang-gu, Goyang-si, Gyeonggi-do, 10264, Republic of Korea
(HO & R&D center) 30, Godeokbizvalley-ro 4-gil, Gangdong-gu, Seoul, 05203, Republic of Korea
SRN: KR-MF-000022760

Authorized representative
Emergo Europe B.V.
Westervoortsedijk, 60
6827 AT Arnhem
Netherlands
SRN: NL-AR-000000116

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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,

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 denominatio n is not obvious)	If the MDR device is a substitute device, identificatio n of the correspondi ng MDD/AIMD D device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile single-use securement devices; (Model: Wing Grip I.V, Wing Grip C.V.C, Wing Grip Foley, Ace Grip, Ace Grip for P.I.C.C, Ace Grip C.V.C, Ace Grip Foley, Ace Grip Levin, Ace Grip Levin Plus, Ace Lock, Ace Lock Plus, Medicover) Basic UDI-DI: 88061396ACE/WINGGRIPsr.SW	Class IS	N/A	N/A	NB1639 KR19/81826 296.00
Sterile single-use blades and stylets for intubation (Model: Ace Blade, Ace Stylet) Basic UDI-DI: 88061396ACEBLADE/STYLET8M	Class IS	N/A	N/A	NB1639 KR19/81826 296.00
Sterile single-use elastomeric infusion pumps (Model: AutoFuser) Sterile single-use elastomeric infusion pumps with flow regulator (Model: AutoSelector) Basic UDI-DI: 88061396AF/ASKB	Class IIa	N/A	N/A	NB1639 KR19/81826 293.00

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 denominatio n is not obvious)	If the MDR device is a substitute device, identificatio n of the correspondi ng MDD/AIMD D device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile single-use elastomeric infusion pumps (Model: AutoFuser S) Sterile single-use elastomeric infusion pumps with flow regulator (Model: AutoSelector S) Basic UDI-DI: 88061396AFS/ASSPB	Class IIa	N/A	N/A	NB1639 KR19/81826 293.00
Sterile single-use PCA infusion pumps (Model: Automed 3200) PCA infusion pump (Model: AutoMed 3300, AutoMed 3400) Sterile single-use reservoir bags and tubing sets (Model: AutoMed Set) Basic UDI-DI: 88061396AUTOMED&SETBQ, EMDN: A030101, A0502	Class IIb	N/A	N/A	NB1639 KR19/81826 293.00

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 denominatio n is not obvious)	If the MDR device is a substitute device, identificatio n of the correspondi ng MDD/AIMD D device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile single-use invasive blood pressure monitoring system (Model: AutoTransducer) Basic UDI-DI: 88061396AUTOTRANSDUCERKF, EMDN: Z120302	Class IIb	N/A	N/A	NB1639 KR19/81826 293.01
Thermal warmers for blood/fluid infusion (Model: AutoMer II) Basic UDI-DI: 88061396AUTOMER55, EMDN: B0401	Class IIb	N/A	N/A	NB1639 KR19/81826 293.00

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
2024/06/11	Version 1	Initial issue