



Taewoong Medical Co., Ltd.  
14 Gojeong-ro, Wolgot-myeon, Gimpo-si,  
Gyeonggi-do, 10022  
Republic of Korea

<29 Feb 2024>

**Confirmation Letter Reference: CLNB1639 – WW/PCI/201809**

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**

Taewoong Medical Co., Ltd.  
14 Gojeong-ro, Wolgot-myeon, Gimpo-si,  
Gyeonggi-do, 10022  
Republic of Korea  
SRN Number : KR-MF-000007515

**Authorized representative**

Emergo Europe B.V.  
Westervoortsedijk, 60  
6827 AT Arnhem  
Netherlands

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 26<sup>th</sup> May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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:

- 26<sup>th</sup> May 2026 for Class III custom-made implantable devices
- 31<sup>st</sup> 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)
- 31<sup>st</sup> December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31<sup>st</sup> 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 1639,



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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)	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
Sterile single-use Guidewire (Optimos™ Guidewire) - 880923433-GW-YS	Class IIa	N/A	NB1639 KR19/81826260
Covered model of - Sterile Niti-S and ComVi Biliary Stents System  Niti-S Biliary Covered Stent [Full-Covered-Type] - 880923310B-BM-FS-65 [Giobor] - 880923310B-M-Gio-C9 [Both Bare-Type] - 880923310B-M-B-UZ [Flare-Type] - 880923310B-BM-F-XN [Kaffes] - 880923310B-BM-Kaf-K5 [Bumpy] - 880923310B-BMP-Bum-8Z  ComVi Biliary Stent [Full Covered-Type, Both Bare-Type, End Bare-Type] - 880923310B-M-ComVi-JA	Class IIb implantable non- WET device		NB1639 KR19/81826260
Covered model of - Sterile Niti-S and ComVi Oesophageal Stents System;  Niti-S Esophageal Covered Stent [Conio] - 880923310E-BMT-1H-K4 [Anti Reflux-Type] - 880923310E-BMT-V-CR [Beta-2] - 880923310E-BMT-Beta-3H	Class IIb implantable non- WET device		NB1639 KR19/81826260

Device name or Basic UDI-DI	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
[Full Covered-Type, Cervical] - 880923310E-BMT-F-B9 [Both Bare-Type] - 880923310E-M-B-W8 [Double Anti Reflux-Type] - 880923310E-M-VX-6A [Double-Type] - 880923310E-M-X-YA			
Covered model of - Sterile Niti-S Tracheobronchial Stents System;  Tracheal [Full Covered-Type] - 880923310Tr-M-F-U2 Bronchial [Full Covered-Type] - 880923310Br-BM-D-VB	Class IIb implantable non- WET device		NB1639 KR19/81826260
Covered model of - Sterile Niti-S and ComVi Pyloric/ Duodenal Stents System;  Sterile Niti-S Pyloric/ Duodenal Stents System [Full Covered-Type] - 880923310P-BM-F-77 [Both Bare-Type, End Bare-Type] - 880923310P-M-Cov-Bare-NN  Sterile ComVi Pyloric/ Duodenal Stents System [Both Bare-Type] - 880923310P-M-ComB-3H [Flare-Type] - 880923310P-M-ComFH-RU	Class IIb implantable non- WET device		NB1639 KR19/81826260

Device name or Basic UDI-DI	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
<p>Covered model of</p> <p>- Sterile Niti-S and ComVi Enteral Colonic Stents System;</p> <p>Sterile Niti-S Enteral Colonic Stents System [Full Covered-Type] - 880923310C-BM-F-Y7 [Both Bare-Type, End Bare-Type] - 880923310C-M-Cov-Bare-5Z</p> <p>Sterile ComVi Enteral Colonic Stents System [Both Bare-Type] - 880923310C-M-ComB-S3</p>	Class IIb implantable non- WET device		NB1639 KR19/81826260
<p>Covered model of</p> <p>- Sterile Niti-S Nagi™ Stent and Niti-S Hot Nagi™ Stent &amp; Electrocautery Stent Delivery System for drainage of pancreatic pseudocyst - 880923310N-P-CK</p>	Class IIb implantable non- WET device		NB1639 KR19/81826260
<p>Covered model of</p> <p>- Sterile Niti-S SPAXUS™ Stent and Niti-S Hot SPAXUS™ Stent &amp; Electrocautery Stents System for drainage of pancreatic pseudocysts - 880923310S-PG-AE</p>	Class IIb implantable non- WET device		NB1639 KR19/81826260
<p>Covered model of</p> <p>- Sterile UVENTA™ Ureteral Stents System -880923310U-M-P-65</p>	Class IIb implantable non- WET device		NB1639 KR19/81826260
<p>Covered model of</p>	Class IIb implantable		NB1639 KR19/81826260

Device name or Basic UDI-DI	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
- Sterile UVENTA™ Urethral Stents System - 880923310U-BM-S-B3	non- WET device		
Uncovered model of - Sterile Niti-S Biliary Stents System; [S-Type, D-Type, M-Type] - 880923310B-M-Unc-EY [LCD-Type] - 880923310B-M-ULCD-KD	Class IIb implantable non- WET device		NB1639 KR19/81826260
Uncovered model of - Sterile Niti-S Pyloric/Duodenal Stents System; [D-Type] - 880923310P-M-UD-A4	Class IIb implantable non- WET device		NB1639 KR19/81826260
Uncovered model of - Sterile Niti-S Enteral Colonic Stents System; [S-Type, D-Type] - 880923310C-M-Uncov-UB	Class IIb implantable non- WET device		NB1639 KR19/81826260

## Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/29	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607