14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022,
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Manufacturer's Declaration to Regulation (EU) 2023/607

According to Regulation (EU)2017/745 (MDR) and regarding the transitional provisions, Taewoong Medical Co., Ltd. declares the amendments to Article 120 of the MDR, as amended by Regulation (EU) 2023/607 applies to the following device(s):

Manufacturer name:	Taewoong Medical Co., Ltd.
Manufacturer address and contact details:	14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Republic of Korea
Single Registration Number (SRN) (if available):	KR-MF-000007515

Authorised Representative name	Emergo Europe BV
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT, Arnhem THE NETHERLANDS
Single Registration Number (SRN)	NL-AR-000000116

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[1]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☑ Expired/expires *after* 20 March 2023:

☑ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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(See Annex I for details about the devices that have been or will be submitted to the notified body for EU MDR review)

☑ We do not intent to lodge an application for conformity assessment by 26 May 2024, there¬fore the transition period will end on 26 May 2024.

(See Annex II for details about the devices that will not be submitted to the notified body for EU MDR review)

➢ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

(MDR EU QMS Certificate (Annex IX QMS) / Certificate Number: KR24/00000045)

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name: Taewoong Medical Co., Ltd.

Location & Date: 14 Gojeong-ro, Wolgotmyeon, Gimpo-si, Gyeonggi-do, 10022, Republic of Korea / July 04, 2024

Signature, Print Name, Title: Yongjin Kim / RA Deputy General Manager 

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Annex I. Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices that have been or will be submitted to the notified body for EU MDR review.

Device identification	Directive Certificate number(s) to which this confirmation is made	Original expiry date[2]	Notified Body name and number	Classification and rule under the MDR	End date of extended validity / transition period
Niti-S Biliary Uncovered Stent [S-Type], Niti-S Biliary Uncovered Stent [D-Type], Niti-S Biliary Uncovered Stent [M-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Uncovered Stent [LCD-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Pyloric/Duodenal Uncovered Stent [D-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Enteral Colonic Uncovered Stent [S-Type], Niti-S Enteral Colonic Uncovered Stent [D-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Covered Stent [Full-Covered-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Covered Stent [Giobor]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Covered Stent [Both Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Covered Stent [Flare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Covered Stent [Kaffes]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Biliary Covered Stent [Bumpy]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
ComVi Biliary Stent [Full Covered-Type], ComVi Biliary Stent [Both Bare-Type], ComVi Biliary Stent [End Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Esophageal Covered Stent [Conio]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Esophageal Covered Stent [Anti Reflux-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Esophageal Covered Stent [Beta-2]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Esophageal Covered Stent [Full Covered-Type], Niti-S Esophageal Covered Stent [Cervical]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027

[2] As indicated on the Directive Certificate prior to the extension of the validity.

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Device identification	Directive Certificate number(s) to which this confirmation is made	Original expiry date[2]	Notified Body name and number	Classification and rule under the MDR	End date of extended validity / transition period
Niti-S Esophageal Covered Stent [Both Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Esophageal Covered Stent [Double Anti Reflux-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Esophageal Covered Stent [Double-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Pyloric/Duodenal Covered Stent [Full Covered-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Pyloric/Duodenal Covered Stent [Both Bare-Type], Niti-S Pyloric/Duodenal Covered Stent [End Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
ComVi Pyloric/Duodenal Stent [Both Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
ComVi Pyloric/Duodenal Stent [Flare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Enteral Colonic Covered Stent [Full Covered-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Enteral Colonic Covered Stent [Both Bare-Type], Niti-S Enteral Colonic Covered Stent [End Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
ComVi Enteral Colonic Stent [Both Bare-Type]	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S Nagi Stent, Niti-S Hot Nagi Stent & Electrocautery Stent Delivery System	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Niti-S SPAXUS™ Stent, Niti-S Hot SPAXUS™ Stent & Electrocautery Stent Delivery System	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIb implantable (Rule 8)	December 31, 2027
Optimos™ Guidewire	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	Class IIa (Rule 7)	December 31, 2028

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Annex II. Schedule of Devices

Following devices will not be submitted to the notified body for EU MDR review.

Device identification	Model number	Directive Certificate number(s)	Original expiry date[3]	Notified Body name and number	End date of extended validity
Niti-S Biliary Uncovered Stent [T,Y-Type]	TTxxyyA, BYxxyyA	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Biliary Covered Stent [Full Covered-Type]	TJxxyyFS	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Esophageal Uncovered Stent	Exxyy, EPxxyy, ETxxyy, ETxxyy-18, ETxxyy-22	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Esophageal Covered Stent [Full Covered-Type]	EKxxyyF	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Pyloric/Duodenal Stent [S-Type]	PTxxyy	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Pyloric/Duodenal Stent [S-Type]	Pxxyy	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
ComVi Pyloric/Duodenal Stent [Flare-Type]	PCxxyyBP	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Enteral Colonic Uncovered Stent [S-Type]	Cxxyy, CxxyyT	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
ComVi Enteral Colonic Stent [Flare-Type]	CCTxxyyP, CCTxxyyP-12	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
ComVi Enteral Colonic Stent [Flare-Type]	CCxxyyBP	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Tracheobronchial Uncovered Stent	BRxxyyW	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Tracheobronchial Uncovered Stent	TRxxyyP	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Tracheal Covered Stent [Full Covered-Type]	TRxxyyFP	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Niti-S Bronchial Covered Stent [Full Covered-Type]	BRxxyyF	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
UVENTA™ Ureteral Stent	UCxxyyFB	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
UVENTA™ Urethral Stent	USxxyyF	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Optimos™ Biopsy Forceps	BFxxyy	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Optimos™ Hook	BHB55, EHB80	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Optimos™ Injector	OIPxxyy-zzG,	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Optimos™ Polypectomy Snare	KSNxxR-yy, KSNxxRN-yy	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024
Optimos™ Stone Basket	SBxxyyF4-zz, SbxxyyF8-zz, SbxxyyT8-zz	KR19/81826260	March 25, 2024	SGS Belgium NV (1639)	May 26, 2024

[3] As indicated on the Directive Certificate prior to the extension of the validity.