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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**Well Lead Medical Co., Ltd.**
Manufacturer address and contact details	C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou, People's Republic of China
Single Registration Number (SRN) (if available)	CN-MF-000006728

Authorised Representative name	**Shanghai International Holding Corp. GmbH (Europe)**
Authorised Representative address and contact details	Eiffestraβe 80, 20537 Hamburg, GERMANY
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	**TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany** **□ See attached schedule**
Notified body number (if applicable)	CE0123 □ See attached schedule

[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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Directive Certificate number(s) to which this confirmation is made (if applicable)	G1S 038814 0090 Rev. 01 G1 038814 0088 Rev.00 G1 038814 0086 Rev.01 G1 038814 0087 Rev.01 G1 038814 0079 Rev. 00 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

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*[2]
- 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 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

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

  ☐ 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), or

[2] 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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☐ 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)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have 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/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have 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/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified 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:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have 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/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 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.

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

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- 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.

Signed for and on behalf of the manufacturer:

Full Company Name: **Well Lead Medical Co., Ltd.**

Location & Date: **Guangzhou, 2024-3-15**

Signature, Print Name, Title:

Chen Yun Gui, Management Representative & PRRC

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Tracheostomy Tube	G1 038814 0079 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Foley Catheter with Temperature Sensor	G1 038814 0079 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Foley Catheter with Temperature Sensor" to "All Silicone Foley Catheter with Temperature Sensor" under MDR .

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Latex Foley Catheter (Model: Hydrophilic Latex Foley Catheter)	G1 038814 0079 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Latex Foley Catheter" to "Hydrophilic Latex Foley Catheter" under MDR and the "Latex Foley Catheter" under Directives contains "Hydrophilic Latex Foley Catheter" .
All Silicone Foley Catheter (Model: Hydrophilic Silicone Foley Catheter)	G1 038814 0079 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "All Silicone Foley Catheter " to "Hydrophilic Silicone Foley Catheter" under MDR and the "All

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
						Silicone Foley Catheter" under Directives contains "Hydrophilic Silicone Foley Catheter" .
Foley Catheter Kit	G1 038814 0079 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Foley Catheter Kit" to "Foley Catheter Tray" under MDR and the "Foley Catheter Kit" under Directives contains "Catheterization Pack" .
Connecting Tube with or without Yankauer Handle	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany	2028-12-31	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
			CE0123	CE0123		
Nelaton Catheter	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
O2+CO2 sampling cannula	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "O2+CO2 sampling cannula" to "ETCO2 sampling cannula" under MDR.
Tracheal Tube	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Laryngeal Mask Device	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	"Laryngeal Mask Device" under Directives contains "PVC Laryngeal

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
						Mask Device" and "Silicone Laryngeal Mask Device" under MDR.
Intubating Stylet	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endotracheal Tube Introducer	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endobronchial Tube	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endobronchial Blocker Tube	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Capnography	G1 038814 0086	2024-05-26	TÜV SÜD Product	TÜV SÜD Product	2028-12-31	Change the device name

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
CO2 Sampling Mask	Rev.01		Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123		from "Capnography CO2 Sampling Mask" to "ETCO2 Sampling Oxygen Mask".
Urethral Catheter	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Silicone Stomach Tube	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	"Stomach Tube" under MDR Contains "Stomach Tube" and "Silicone Stomach Tube" under Directives.
Stomach Tube	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	"Stomach Tube" under MDR contains "Stomach

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						Tube" and "Silicone Stomach Tube" under Directives.
Suction ToothBrush	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Bile T-Tube	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Intermittent Catheter	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endotracheal Tube Kit	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Endotracheal Tube Kit" to "Tracheal Tube Kit" under MDR.

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Reinforced Endotracheal Tube	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Endotracheal Tube with Evacuation Lumen	G1 038814 0086 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Endotracheal Tube with Evacuation Lumen" to "Tracheal Tube with Evacuation Lumen" under MDR.
Drainage System	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Silicone Drainage System	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	"Drainage System" contains "Silicone Drainage System" under MDR.

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Oxygen Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Breathing Circuit	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Breathing Circuit" to "Heated Breathing Circuit" under MDR.
Anesthetic Breathing Circuit	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	1. Change the device name from "Anesthetic Breathing Circuit" to "Anesthesia Breathing Circuit Kit" under MDR. 2. Anesthetic Breathing Circuit included in

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
						Anesthesia Breathing Circuit Kit under MDR certificate.
Anesthetic Breathing Circuit Kit	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Anesthetic Breathing Circuit Kit" to "Anesthesia Breathing Circuit Kit" under MDR.
Extraction Bag (Operation Use)	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from " Extraction Bag (Operation Use)" to " Extraction Bag " under MDR.
Ureteral Stent Set	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339,	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339,	2028-12-31	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
			München, Germany CE0123	München, Germany CE0123		
Ureteral Stent	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	"Ureteral Stent Set" contains "Ureteral Stent "under MDR.
Urodynamic Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Ureteral Access Sheath	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Ureteral Dilation Balloon Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Ureteral Dilator	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Urethral Dilator	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Urological Guide Wire	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Dilation Set	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from " Dilation Set" to " Percutaneous Nephrostomy Kit " under MDR.
Stone Retrieval Basket	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oxygen Tubing	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany	2028-12-31	

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			CE0123	CE0123		
Catheter Mount	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Gas Sampling Line	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Tube Accessories for Urodynamic Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Suprapubic Catheter Set	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Rectal Pressure Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Suction-Evacuation	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH,	TÜV SÜD Product Service GmbH,	2028-12-31	Change the device name

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Access Sheath			Ridlerstr. 65, 80339, München, Germany CE0123	Ridlerstr. 65, 80339, München, Germany CE0123		from " Suction-Evacuation Access Sheath" to "Suction Evacuation Access Sheath " under MDR.
Ureteral Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Nephrostomy Access Sheath Set	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Nephrostomy Access Sheath Set" to "Suction-Evacuation Nephrostomy Access Sheath Set" under MDR.

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Urinary Nephrostomy Catheter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Vacuum Interrupter	G1 038814 0087 Rev.01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oxygen Mask	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Non-Rebreath Mask	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Multi-vent Mask	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Suction Catheter	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339,	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339,	2028-12-31	

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			München, Germany CE0123	München, Germany CE0123		
Nasal Oxygen Cannula	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Aerosol Mask	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Aerosol Mask" to "Nebulizer Kit" and the "Nebulizer Kit" under MDR contains "Aerosol Mask" .
Nebulizer	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Nebulizer" to "Nebulizer Kit" and the "Nebulizer Kit" under MDR

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						contains "Nebulizer" .
Disposable Air Cushion Face Mask	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Nasal Jet Tube	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Feeding Tube	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Tracheostomy Mask	G1 038814 0088 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Oropharyngeal Airway	G1S 038814 0090 Rev. 01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Nasopharyngeal	G1S 038814	2024-05-26	TÜV SÜD Product	TÜV SÜD Product	2028-12-31	

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Airway	0090 Rev. 01		Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123		
Endoscopic Seal	G1S 038814 0090 Rev. 01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	
Stone Collection Bottle	G1S 038814 0090 Rev. 01	2024-05-26	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany CE0123	2028-12-31	Change the device name from "Stone Collection Bottle" to "Specimen Collection Bottle" under MDR.

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