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Declaration for the Compliance with the Criteria Set Out in REGULATION (EU)2023/607 For the Extension of the Validity of EC Certificate

SECURMED SPA

Viale Piane Nocella 23_ 64012 Campli

(TE)

SRN:IT-MF-000033596

The EC Certificate, G2 036310 0041 Rev. 00, issued by TÜV SÜD Product Service GmbH, Ridlerstraße 65 80339 Munich Germany on the date of 2019-08-08 , are with expiry date of2024-05-26, which is after the date of entry of the amendment, 15th March 2023.
The risk class of the devices, NELATON CATHETERS Securdrain Via'!, SUCTION CATHETERS Securflow và! and CONNECTING TUBES Securflow và! are Class IIa respectively according to Regulation (EU) 2017/745 . Therefore,the validity of certificate G2 036310 0041 Rev. 00, are extended through 31st December 2028, according to Regulation (EU) 2023/607. A full list of devices that will be benefiting from the extension of the Validity of CE Certificate can be located inAppendix A of this document.
The Notified Body, TÜV SÜD Product Service, that issued the EC Certificate, G2 036310 0041 Rev.00, will transfer the appropriate surveillance activities according to Article 120 (3e) of Regulation(EU) 2017/745 in respect of legacy devices covered by a certificate issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC to the incoming Notified Body IMQ S.p.A. via Quintiliano 43 20138 Milan (MI), Italy .

SECURMED SPA declares that the following criteria set out in REGULATION (EU) 2023/607 are met to make them eligible for the extension of the validity of the EC Certificate

√ QMS is in place in accordance with Article 10(9) MDR since June 20, 2023.
√ The contract for MDR conformity assessment was signed by Notified Body, IMQ on 21 december 2023with contract number: 1002C03093368C
√ There are no significant changes in the design.
√ There is no change in the intended use of the devices.
√ The devices do not present an unacceptable risk.
√ The devices continue to comply with Directive 93/42/EEC MDD, as applicable.
√ The MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration ofeconomic operators and of devices are met.
√ Notified Body IMQ IS responsible for the surveillance of the device.

Name: GABRIELE GIOVANELLI Position: Management Representative

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1 As amended by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March2023

Appendix A – List of Devices Benefiting from Extension of the Validity of EC Certificates Product Details, Names or Trade Names	**Certificate No.**	**Classification**
Device 1 NELATON CATHETER Securdrain Và! (Basic UDI - DI: **8025500cat003STSMKW)**	G2 036310 0041 Rev. 00	Class IIa
Device 2 SUCTION CATHETER Securflow Và! (Basic UDI -DI: **8025500son004STSM9C)**	G2 036310 0041 Rev. 00	Class IIa
Device 3 CONNECTING TUBE Securflow Và! (Basic UDI - DI: **8025500pro005STSM9Q)**	G2 036310 0041 Rev. 00	Class IIa

SELF DECLARATION

We, SECURMED SPA confirm that, our existing MDD Certificate (No G2 036310 0041 Rev. 00) which expires on 2024-05-26, will benefit from the MDR transition period until 31st December 2028, taking into consideration the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devicesand in vitro diagnostic medical devices.

The required contract for MDR conformity assessment has already been signed by our NotifiedBody,IMQ S.p.A. via Quintiliano 43 20138 Milan (MI), Italy .

We confirm that all the products that are listed in the above mentioned certificate will benefitfrom this transition.

Authorized Signature:Date: 03/10/2024