winner
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Manufacturer's Confirmation in regard to Regulation 2023/607

with respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ("Directive Certificates") and their validity per Article 120(2) of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ("MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market as per Article 120(3) of the MDR

Manufacturer name	Winner Medical Co., Ltd.
Manufacturer address	Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Manufacturer EUDAMED SRN	CN-MF-000005692
Notified Body name	TÜV SÜD Product Service GmbH
Notified Body number	0123

This is confirmation that the devices listed below meet following conditions for extension of certificates issued under Council Directive Council Directive 93/42/EEC on medical devices (MDD) as stated in Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 on medical devices

- The certificate(s) covering the listed devices was valid on the 26 May 2023.
- The device(s) continue to comply with Directive 93/42/EEC (MDD)
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The device(s) do not present unacceptable risks to health or safety of patients, users or other persons, or to other aspects of the protection of public health
- A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) has been put in place by the manufacturer no later than 26 May 2024.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) listed and a signed written agreement is in place in accordance with Section 4.3, second subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR). This was completed prior to the expiry of the certificate
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Signature: SHANGGUAN, Ziling

Date: January 9, 2024

Print name: SHANGGUAN, Ziling

Title/position: Regulatory Affairs Specialist

Schedule of devices

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66803131	Sterile Silicone SAD 10x10cm,1S, EO	No. G1 046241 0065 Rev.04	2024-05-26	2028-12-31
66803132	Sterile Silicone SAD 15x20cm,1S, EO	No. G1 046241 0065 Rev.04	2024-05-26	2028-12-31
66803133	Sterile Silicone SAD 20x20cm,1S, EO	No. G1 046241 0065 Rev.04	2024-05-26	2028-12-31
66803134	Sterile Silicone SAD 20x25cm,1S, EO	No. G1 046241 0065 Rev.04	2024-05-26	2028-12-31
66803135	Sterile Silicone SAD 20x40cm,1S, EO	No. G1 046241 0065 Rev.04	2024-05-26	2028-12-31