

文件编号: SU/CE-FAK-07 (A/0)

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Danyang Sunmed Healthcare Corporation NO.3 Bei Er Huan, Danyang, Jiangsu, China
Trademark:	N.A
SRN:	CN-MF-000013734
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001
Importer:	XD Connects B.V. Lange Kleiweg 6-28, 2288 GK Rijswijk, The Netherlands
Trade name:	First Aid Kit
Product Name:	First Aid Kit
Models:	P265.12X, P265.31X, P265.4XX
EMDN:	V0501
Basic UDI-DI:	697456746000266C
Classification acc. to MDR Ax. VIII:	Class Is, rule 4 & rule 1
Applied Standard & Common Specification:	EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10
Conformity assessment procedure:	article 19 + annex II + annex III
CE certificate No.:	No. G21 06069 0025 Rev. 00
Name and ID of the Notified	TUV SUD Product Service GmbH 0123

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). The products combined together are compatible. All supporting documentations are retained under the premises of the manufacturer.

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Weiliang Sun,
General Manager

Danyang, May, 22. 2026