Certificate of Registration

KB International

Registration No.: EAR/PK/7279

This is to certify that KB International is agree to perform all duties and responsibilities as the European Authorized Representative for the below mentioned manufacturer.

Manufacturer Name: Swantia Medical (Pvt) Ltd. SRN # PK-MF-000036302

Address: P.O.S.I Estate, Defence Road, Sialkot 51310, Pakistan

And

European Authorised Representitive: KB INTERNATIONAL SRN # HU-AR-000034102

Address: Auróra utca, 13. al. 1, Budapest - 1084, Hungary

Product Category: Surgical & Dental Instruments (See Annex A for Product List)

Classification: Class I

The product(s) category described mentioned above is in conformity with:
Applicable conformity assessment procedure as per article 52, EU MDR 2017/745.

Manufacturer issued the Declaration of Conformity and conforms that above-mentioned products meets the requirements of Medical Device Regulation and the relevant applicable standards. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

AR Start: 25-10-2024 AR End: 24-10-2025

E.A.R KB INTL HU-AR-000034102 WWW.KB-INTL.COM

Managing Director

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KB INTERNATIONAL (EAR SRN # HU-AR-000034102)
Auróra utca, 13. al. 1, 1084 - Budapest, Hungary
Web: www.kb-intl.com Email: info@kb-intl.com Tel: +36 70 6790786

The certificate remains valid until the expiration agreement of EAR agreement, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits. The product liability rests with the manufacturer in accordance with applicable regulations and standards, after fulfiling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all products of the brand included in the mandate written.

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Annex A
Registration No.: EAR/PK/7279

Sr.#	Product Name	Risk Class	GMDN	BASIC UDI-DI
1	Laryngoscope Blade, Reusable	Class I	46827	++G640RLARYB6L
2	Flexible-End Laryngoscope Blade	Class I	46829	++G640RFLXELB78
3	Laryngoscope Handle, Reusable	Class I	46830	++G640RLARYH6Y
4	Airway Tube Forceps, Reusable	Class I	31264	++G640RAIRTF4C
5	Laryngoscope Blade, Single-Use	Class I	46828	++G640SLBUL
6	Laryngoscope Handle, Single-Use	Class I	47806	++G640SLHUY
7	Rigid Intubation Laryngoscope, Reusable	Class I	15076	++G640RRILGP
8	Rigid Intubation Laryngoscope, Single-Use	Class I	62918	++G640SRILGW

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