FM Deura & Co.

EC DECLARATION OF CONFORMITY

Date of Issuance 28-07-2021 Valid till 28-07- 2026

FM Deura& Co.
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Is registered in EUDAMED with SRN number **PK-MF-000010060.**
and Competent Authority ''Swedish Medical Products Agency – Läkemedelsverket'' with diary number 6.6 1-2021-58819.

Hereby declares that EC Representative had been appointed as follow for
Medical Devices (Class I – Reusable)
IBC – Sweden
14564 Norsborg
Stockholm, Sweden
Email: eurep@ibcsweden.eu

We hereby declare that the EC declaration of conformity is issued under the sole responsibility of the FM Deura& Co. as per Article 19 and Annex IV and tends to meet the essential and applicable requirements as per Annex IV under Regulation (EU) 2017/745 [MDR 2017/745 for CE] . Medical Devices attached in Annex A are in conformity with the MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of Official Journal of the European Union, are applied where applicable and presumed to be in conformity with the requirements of ''Risk class I'' of the device in accordance with the rules set out in Annex VIII covered by those standards or parts thereof.

The products manufactured are provided in Annex A of this EC Declaration of conformity. The products declared in Annex A are in compliance to applicable standards and or are harmonized by EU Medical Device Regulation 2017/745 and Swedish Medical Products Agency – Läkemedelsverket. The traceability of the device covered by the EU declaration of conformity are in compliance where appropriate (Quality Management System and UDI protocols, as well as its intended purpose.

We also declare; Products mentioned in Annex A of this declaration are in conformity with applicable general safety and performance requirements given in Annex I of MDR 2017/745 under the conditions of the intended use of the device, Documents will be presented upon request by a Swedish Medical Products Agency – Läkemedelsverket, the indicated therein, FM Deura& Co.will provide that technical documentation in its entirety and summary thereof.

FM Deura & Co. Proprietor

The products manufactured are Reusable - Class I (Non-Sterilized), lower risk products in line with Annex VIII;

The products referred to Annex A are developed with due care in lieu of technical documentation referred to in Annexes II and III of MDR 2017/745 and harmonized standards given in Annex B of this declaration.

To keep the technical documentation, the EU declaration of conformity andrelevant certificates, including any amendments and supplements, issued in accordance with Article 56, availablefor the Swedish Medical Products Agency – Läkemedelsverket for a period of at least 10 years after the last device covered by the EU declaration ofconformity has been placed on the market.

The Basic UDI-DI as referred to in Part C of Annex VI had been established in reference to product in Annex A as per information to be submitted upon the registration of Devices and Economic Operators in accordance with articles 28, 29 and 31.

FM Deura & Co.

Annex A

Product List

Declares that products list has been classified as Medical Devices (Class I – Reusable) inclusive of mentioned product variant sis in conformity with the essential requirements, provisions of Medical Device Regulation 2017/745 and Swedish Medical Products Agency – Läkemedelsverket. IBC – Sweden had been appointed as EC Representative for following products.

Sr. No.	Product Group	RISK CLASS	PRODUCT INFORMATION	PRODUCT CODE (FMD)	PRODUCT CODE (COMED)	BASIC UDI-DI
1	Scissors	CLASS 1	UTILITY SCISSORS 7-1/2" (RED HANDLE)	01US01	29 102 40	896400314201US01743G
			UTILITY SCISSORS 7-1/2" (BLUE HANDLE)	01US02	29 102 41	
			UTILITY SCISSORS 7-1/2" (YELLOW HANDLE)	01US03	29 102 42	
			UTILITY SCISSORS 7-1/2" (BLACK HANDLE)	01US04	29 102 45	
			MAYO SCISSORS 14CM STARIGHT	02US11	C1 050 14	
			MAYO SCISSORS 14CM CURVED	02US12	C1 051 14	
			KELLY SCISSORS 16CM STRAIGHT	03US21	C1 165 16	
			IRIS SCISSORS 11CM STRAIGHT	04US31	C1 060 11	
			ISIS SCISSORS 11CM CURVED	04US32	C1 061 11	
			SPENCER/STICH SCISSORS 11CM STRAIGHT	05US41	C1 150 11	

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2	Forceps	CLASS 1	POZZI FORCEPS 24CM STRAIGHT	06GF75	C2 280 24	896400314206GF750003A
			BANGOLEA FORCEPS STRAIGHT 20CM	07GF85	C2 270 20	
			MICHEL DOUBLE USE FORCEPS 13 cm	08GF95	C2 400 13	
			FIELCHENFELD FORCEPS 09CM	09GF101	C1 500 09	
			FIELCHENFELD FORCEPS 11CM	09GF102	C1 500 11	
			ADSON FORCEPS 12CM NO TEETH	10GF125	C2 300 00	
			MAYO HEGAR NEEDLE HOLDER 14CM	11GF151	C3 010 14	
3	Operating Scissors	CLASS 1	OPERATING SCISSORS B/B 14 CM STRAIGHT	12OS201	C1 001 14	896400314212OS201224HX
4	Tweezers	CLASS 1	LONDON COLLEGE TWEEZERS 14 CM	12GT225	C1 440 15	896400314213GT225250G2
			DISSECTING FORCEPS 14CM 1X2 TEETH	12GT235	C1 400 14	
5	Vaginal Specula	CLASS 1	COLLIN VAGINAL SPECULUM 38 x 120	14VS251	C8 021 38	896400314214VS251274RQ
			COLLIN VAGINAL SPECULUM 40 x 120	14VS252	C8 021 40	
			CUSCO VAGINAL SPECULUM LARGE 100 x 37 cm	14VS260	C8 020 03	
6	Shears	CLASS 1	BRUN PLASTER SHEARS 23CM	15GS275	47 310 23	896400314215GS275300JC

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Annex B

The products mentioned in Annex A of this declaration are hereby declared in conformity with applicable harmonized standard mentioned below.

Standards	Description
Medical devices-Application of risk management to medical Devices	ISO 14971
Medical Device Regulation (MDR)	Regulation (EU) 2017/745
Medical devices-Quality management systems-Requirements for regulatory purposes.	EN ISO 13485: 2016
Biological evaluation of medical devices-Part 1: Evaluation and testing	ISO10993-1
Biological evaluation of medical devices -Part 2: Animal welfare requirements	ISO10993-2
Biological evaluation of medical Devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO10993-3
Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol	ISO 15223-2:2010
Graphical Symbols for Use in the Labeling of Medical Devices	ISO 15223-1
Guide line for authorized representatives	MEDDEV 2.5. /10
Medical device classification	MEDDEV 2.4/1
Evaluation of clinical data- guide for manufacturer and notified bodies	MEDDEV 2.7.1 Appendix-1
Medical device vigilance system	MEDDEV 2.12.1
Standard Specification for Stainless Steel Billet, Bar, and Wire forSurgical Instruments	ASTM-F899
Surgical Instruments – Metallic Materials – Part 1: Stainless Steel	ISO 7153-1
Sterilization of Health care products	ISO 17665-1
Competent Authority (Swedish Medical Products Agency – Läkemedelsverket)	Medical Devices Act HSLF-FS2021:32and the Swedish Medicine Agency`sRegulations, LVFS 2003:11 or LVFS 2001:7. 2021:43

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