

Document No.	077-17649-00	Title:	Midmark and Ritter Barrier-Free Examination Chair, EU MDR Declaration of Conformity	
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This Declaration of Conformity is issued under the sole responsibility of Midmark Corporation. The device(s) covered by the present Declaration is in conformity with all applicable regulations or directives, including compliance with related Essential Requirements and General Safety and Performance Requirements.

Object of the declaration:

Legal Manufacturer	 Midmark Corporation 60 Vista Drive Versailles, OH 45380 U.S.A.
Authorized Representative	 CEpartner4U Esdoornlaan 13 3951 DB Maarn, The Netherlands
Applicable Regulations and Directives covered by this Declaration	Restriction of Hazardous Substances Directive, 2011/65/EU European Union Medical Device Regulation 2017/745
Product Name	Midmark and Ritter Barrier-Free Examination Chair
Basic UDI-DI	00841709118685GW
SRN	US-MF-000002581
Risk Classification	Class I per Annex VIII, Rule 1 and Rule 13
Intended Purpose	The examination chair is intended to be used as a chair / table to provide positioning and support of patients during general examination procedures conducted by medical professionals.
Relevant Harmonized Standards	Reference Appendix B of 077-1246-10
Common Specification (if applicable)	Not Applicable
Name and address of Notified Body (if applicable)	Not Applicable
Applicable CE Certificate(s)	Not Applicable
Identification of the person authorized to sign on behalf of Midmark Corporation:	Name: Kathy Baughman Signature:  Title: Director of Quality and Regulatory Place of Issue: Versailles, OH 45380 Date: 

Pathway to Conformance for CE Mark is demonstrated according to Regulation MDR 2017/745: Annex II and Annex III (Technical Documentation)

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Device Name	Device Model No.	UDI-DI	EMDN Code	DoC, Date of First Issue
Ritter Barrier-Free Examination Chair	224-011	00841709106026	V08020101	May 26, 2020
Midmark Barrier-Free Examination Chair	627-011	00841709105968	V08020101	May 26, 2020

Accessory Name	Accessory Model No.	UDI-DI	EMDN Code	DoC, Date of First Issue
Patient Support Rails	9A600001	00841709106170	V0880	May 26, 2020
Patient Support Rails Plus	9A600002	00841709106187	V0880	May 26, 2020
Assist Arms	9A615001	00841709117992	V0880	May 26, 2020
Articulating Knee Crutch	9A645001	00841709113277	V0880	May 26, 2020
Standard Knee Crutch	9A643001	00841709113260	V0880	May 26, 2020
Standard Knee Crutch without Mounting Bracket	9A678001	00841709113284	V0880	May 26, 2020
Articulating Knee Crutch without Mounting Bracket	9A679001	00841709113291	V0880	May 26, 2020
Treatment Pan	9A610001	00841709117985	V0880	May 26, 2020

DOCUMENT REVISION HISTORY

ECO NO.	AUTHOR	DESCRIPTION OF REVISION	REV
ECO083024	S. Baker	Initial Release	AA1
ECO089218	S. Baker	Updated to include Basic UDI-DI, SRN and EMDN Codes	AA2
ECO091078	S. Baker	Added statement "Pathway to Conformance for CE Mark is demonstrated according to Regulation MDR 2017/745: Annex II and Annex III (Technical Documentation)"	AA3