

Document No.	077-17650-00	Title:	Ritter 204 -013 and -014 EU MDR Manual Examination Table, 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	Ritter 204 Manual Examination Table
Basic UDI-DI	00841709118708GH
SRN	US-MF-000002581
Risk Classification	Class I per Annex VIII, Rule 1
Intended Purpose	This table is intended for used as a table to provide positioning and support of patients during examination procedures conducted by qualified medical professionals in an office environment.
Relevant Harmonized Standards	Refer to Annex B of 077-1182-08
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 204 Medical Examination Table	204-013	00841709106224	V080202	May 26, 2020
Ritter 204 Medical Examination Table	204-014	00841709106231	V080202	May 26, 2020

Accessory Name	Accessory Model No.	UDI-DI	EMDN Code	DoC, Date of First Issue
FIXED KNEE CRUTCH	9A410001	00841709113178	V0880	May 26, 2020
FIXED KNEE CRUTCH W/ SPLINE	9A410004	00841709113192	V0880	May 26, 2020
ARTICULATING KNEE CRUTCH	9A411001	00841709113215	V0880	May 26, 2020
ARTICULATING KNEE CRUTCH W/ SPLINE	9A411004	00841709113239	V0880	May 26, 2020
ASSIST HANDLES	9A632001	00841709111068	V0880	May 26, 2020
STAINLESS STEEL DRAIN PAN	9A70000	00841709118029	V0880	May 26, 2020
ARTICULATING ARM REST (PAIR)	9A627001	00841709113253	V0880	May 26, 2020

DOCUMENT REVISION HISTORY

ECO NO.	AUTHOR	DESCRIPTION OF REVISION	REV
ECO083024	S. Baker	Initial Release	AA1
ECO086372	S. Baker	Clerical error on first page stated the product was a chair and not a table. Error corrected.	AA2
ECO089218	S. Baker	Clerical error on page 2. Correction from 204-104 to 204-014, review of intended purpose statement for accuracy and also included Basic UDI-DI, SRN, and EMDN Codes	AA3
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)"	AA4