


EU Declaration of Conformity

Hi-Riser Changing Bench

Technical Documentation Reference: SMUK MDRTD 007

This Declaration of Conformity is issued under the sole responsibility of the Prism medical UK. We hereby declare that the mentioned product/ attached list of product comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745

Legal Manufacturer:	Smirthwaite 16 Wentworth Road Heathfield Industrial Estate, Newton Abbot TQ12 6TL ·	
SRN	GB-MF-000010683	
Authorized Representative:	European Healthcare & Device Solutions (Ireland) Ltd Stratton House, Bishopstown Road, Cork Ireland T12 Y9TC	
Product Name:	Hi-Riser Changing Bench	
GMDN Code and Title:	43600 -Bathing/changing table, stationary	
CND nomenclature	Y093312 – Shower, Stretcher	
Basic UDI-DI	50564089SMUK008TH	
Identification of the device(s) concerned:	Full List of Product Codes or Ref. to Product Range Table in appendix 1	
Catalogue Number:	Full List of Product Codes or Ref. to Product Range Table in appendix 1	
Intended purpose:	intended to support a recumbent patient for changing purposes	
Risk Classification:	Class 1 as per Rule 13 in Annex VIII	
Conformity Assessment Route:	Annex II and III of EU Medical Device Regulation (EU) 2017/745	
Relevant Harmonized Standards	ISO 14971:2019 EN ISO 15223-1:2016 BS EN 12182:2012	EN 62366-1:2015 EN/IEC 60601-1: 2006
References to any CS:	N/A	
Identification of Notified Body:	N/A	
Identification of the Certificate(s):	N/A – Class I self certified device	
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Paul Morton Signature:  Chief Executive Officer Place of Issue: Grange Moor, England Date: 23 th Aug 2021	

List of Products

ICC code	Description	SWL
3041	Hi-Riser Changing bench - Size 1 – Mild Steel	200kg
3042	Hi-Riser Changing bench - Size 2 – Mild Steel	200kg
3043	Hi-Riser Changing bench - Size 3 – Mild Steel	200kg
3044	Hi-Riser Changing bench - Size 4 – Mild Steel	200kg
3045	Hi-Riser Changing bench - Size 5 – Mild Steel	200kg
3046	Hi-Riser Changing bench - Size 6 – Mild Steel	200kg
3047	Hi-Riser Changing bench - Size 7– Mild Steel	200kg
3048	Hi-Riser Changing bench - Size 8 – Mild Steel	200kg
3049	Hi-Riser Changing bench - Size 9 – Mild Steel	200kg
3051	Hi-Riser Changing bench - Size 1 – Stainless steel	200kg
3052	Hi-Riser Changing bench - Size 2 – Stainless steel	200kg
3053	Hi-Riser Changing bench - Size 3 – Stainless steel	200kg
3054	Hi-Riser Changing bench - Size 4 – Stainless steel	200kg
3055	Hi-Riser Changing bench - Size 5 – Stainless steel	200kg
3056	Hi-Riser Changing bench - Size 6 – Stainless steel	200kg
3057	Hi-Riser Changing bench - Size 7 – Stainless steel	200kg
3058	Hi-Riser Changing bench - Size 8 – Stainless steel	200kg
3059	Hi-Riser Changing bench - Size 9 – Stainless steel	200kg

Revision History

Rev Number	Date	Comment	Author
1.0	23 Aug 2021	Initial issue of CE Certificate under EU Medical Device Regulation (EU) 2017/745.	EJ