


EU Declaration of Conformity

Heathfield Chair

Technical Documentation Reference: SMUK MDRTD 001

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	TBD
Authorized Representative:	European Healthcare & Device Solutions (Ireland) Ltd Stratton House, Bishopstown Road, Cork Ireland T12 Y9TC
Product Name:	Heathfield Chair & accessories
GMDN Code and Title:	58827 - Assistive ergonomic chair
CND nomenclature	Y180939 – Postural systems, modular and customed
Basic UDI-DI	50564089SMUK002T5
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 provide postural support
Risk Classification:	Class 1 as per Rule 1 in Annex VIII
Conformity Assessment Route:	Annex II and III of EU Medical Device Regulation (EU) 2017/745
Relevant Harmonized Standards	EN ISO 13485:2016 ISO 14971:2012 EN ISO 15223-1:2016 BS EN 12182:2012 EN 62366-1:2015
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 Commercial Officer Place of Issue: Grange Moor, Egnland Date: 3 rd June 2021

List of Products

ICC code	Description
6901	Heathfield size 1 adjustable arm
6902	Heathfield size 2 adjustable arm
6903	Heathfield size 3 adjustable arm
6904	Heathfield size 4 adjustable arm
6905	Heathfield size 5 adjustable arm
6906	Heathfield size 6 adjustable arm
6911	Heathfield size 1 Fixed Arm
6912	Heathfield size 2 Fixed Arm
6913	Heathfield size 3 Fixed Arm
6914	Heathfield size 4 Fixed Arm
6915	Heathfield size 5 Fixed Arm
6916	Heathfield size 6 Fixed Arm

Accessories	SIZE 1	SIZE 2	SIZE 3	SIZE 4	SIZE 5	SIZE 6
	CODE	CODE	CODE	CODE	CODE	CODE
skis	SK001	SK002	SK003	SK004	SK005	SK006
ski & half footrest	SK012	SK013	SK014	SK015	SK016	SK017
ski & full footrest	SK023	SK024	SK025	SK026	SK027	SK028
reversible footboard	FB006	FB007	FB008	FB009	FB010	FB011
adjustable footrest	FR005	FR006	FR007	FR008	FR009	FR009
independent adjustable footrest	4187	4187	4187	4187	4187	4187
kicking board	KB001	KB002	KB003	KB004	KB005	KB005
mobile dolly base	DL006	DL007	DL008	DL009	DL010	DL011
minimum raise mobile base	N/A	N/A	MB005	MB006	MB007	MB008
footplate and straps	FP001	FP002	FP003	FP004	FP005	FP005
knee blocks	N/A	N/A	KN001	KN001	KN001	KN001
pommel	PL001	PL002	PL013	PL014	PL014	PL014
independent adjustable split seat	N/A	N/A	SE031	SE032	SE033	SE034
quick release tray	TR101	TR102	TR103	TR104	N/A	N/A
wooden tray	TR071	TR072	TR073	TR074	TR005	TR005
tray handrail full width	HR001	HR001	HR002	HR002	HR003	HR003
tray handrail half width	HR004	HR004	HR004	HR004	HR004	HR004
lumbar pad	PD001	PD002	PD003	PD004	PD005	PD005
sacral pad	PD012	PD013	PD014	PD015	PD016	PD016
higher backrest in lieu of standard	BK170	BK171	BK172	BK173	BK174	BK174
25mm pelvic cushions (pair)	CS005	CS005	CS006	CS007	CS008	CS009

38mm pelvic cushions (pair)	CS014	CS014	CS015	CS016	CS017	CS018
50mm pelvic cushions (pair)	CS023	CS023	CS024	CS025	CS026	CS027
62mm pelvic cushions (pair)	CS032	CS032	CS033	CS034	CS035	CS036
75mm pelvic cushions (pair)	CS041	CS041	CS042	CS043	CS044	CS045
25 + 25mm pelvic cushion (pair)	CS050	CS050	CS051	CS052	CS053	CS054
38 + 25mm pelvic cushion (pair)	CS230	CS230	CS232	CS233	CS234	CS235
50 + 25mm pelvic cushion (pair)	CS077	CS077	CS078	CS079	CS080	CS081
62 + 25mm pelvic cushion (pair)	CS086	CS086	CS087	CS088	CS089	CS090
75 + 50mm pelvic wedge cushion (pair)	CS095	CS095	CS096	CS097	CS098	CS099
75 + 62mm pelvic wedge cushion (pair)	CS104	CS104	CS105	CS106	CS107	CS108
75 + 75mm pelvic wedge cushion (pair)	CS113	CS113	CS114	CS115	CS116	CS117
75 + 100mm pelvic wedge cushions (pair)	CS122	CS122	CS123	CS124	CS125	CS126
groin harness	HN039	HN039	HN040	HN040	HN041	HN041
four point harness	HN001	HN002	HN003	HN003	HN004	HN004
waistcoat harness	HN009	HN009	HN010	HN010	HN011	HN011
adjustable height push handle	PH010	PH011	PH012	PH013	PH014	PH015
fixed height push handle	PH004	PH005	PH006	PH007	PH008	PH009
4 glisdomes complete with screws	GD001	GD001	GD001	GD001	GD001	GD001

Revision History

Rev Number	Date	Comment	Author
1.0	26 May 2021	Initial issue of CE Certificate under EU Medical Device Regulation (EU) 2017/745.	EJ
2.0	03 June 2021	Correction to Intended Purpose	EJ