



EU-declaration of conformity

As manufacturer
ROHO, Inc.
1501 South 74th St.
Belleville, IL 62223 U.S.A.

declares under the sole responsibility that below specified product is in conformity with the

Regulation (EU) 2017/745
on medical devices (MDR)
ROHO, Inc. is a subsidiary of Permobil, Inc.

Trade Name:

ROHO® AGILITY® Max Contour Back Support
ROHO® AGILITY® Back Support Quick Release Hardware
ROHO® AGILITY® Back Support Direct Mount Hardware
ROHO® AGILITY® UniTrack Rail

General Description:

AGILITY

Intended Use: The ROHO AGILITY Max Contour Back Support (AGILITY Max) is a replacement backrest for wheelchairs that is intended to provide trunk/pelvis support and positioning. AGILITY has a weight limit of 300 lbs. (136 kg) and must be properly sized to the individual.

Intended Use: ROHO AGILITY Back Support Quick Release Hardware (AGILITY Quick Release Hardware) is intended to attach compatible ROHO AGILITY Back Supports to the wheelchair back canes

Intended Use: The ROHO AGILITY Back Support Direct Mount Hardware (AGILITY Direct Mount Hardware) is intended to attach compatible ROHO AGILITY Back Supports to Permobil power wheelchairs that have compatible Corpus seating and a weight limit that does not exceed 300 lbs. (136 kg).

Intended Use: The ROHO AGILITY UniTrack Rail (AGILITY UniTrack Rail) is an interface rail intended to attach the hardware for a Permobil head support to compatible ROHO AGILITY Back Supports.

The manufacturer's internal article number(s) is/are:

Back Support	Hardware
AG6-1416AL-0	AG-HDWR-DM14
AG6-1418AL-0	AG-HDWR-DM15
AG6-1420AL-0	AG-HDWR-DM16
AG6-1516AL-0	AG-HDWR-DM17
AG6-1518AL-0	AG-HDWR-DM18
AG6-1520AL-0	AG-HDWR-DM19
AG6-1616AL-0	AG-HDWR-DM20
AG6-1618AL-0	AG-HDWR-QR
AG6-1620AL-0	AG-HR-UT
AG6-1716AL-0	AG-HR-UT14
AG6-1718AL-0	AG6DEMO
AG6-1720AL-0	
AG6-1816AL-0	

AG6-1818AL-0
AG6-1820AL-0
AG6-1916AL-0
AG6-1918AL-0
AG6-1920AL-0
AG6-2016AL-0
AG6-2018AL-0
AG6-2020AL-0

Basic UDI-DI: Back: 613732AGBSEU

Manufacturer SRN: US-MF-000018363

Authorized representative: MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Authorized representative SRN: DE-AR-000005430

Product class: Class I (according to Annex VIII Chapter III, rule 1)

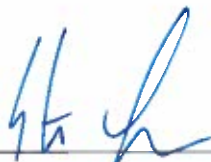
Conformity procedure used: EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III

Standards: Conformity to the general safety and performance requirements have been demonstrated by using the following standards:
EN 12182:2012
ISO 14971:2019
EN ISO 13485:2016
EN ISO 10993-1:2020
EN 1021-1:2014
EN 1021-2:2014
ISO 13732-1:2008
ISO 15223-1:2021
ISO 16840-6:2015
ISO 7176-8:2014(E)

Original drawn up: 2020-11-11

Place and date: Belleville, Illinois, USA
2025-02-21

On behalf of ROHO, Inc.



Steven Louer
Senior Manager QA/RC