

EU-declaration of conformity

As manufacturer
ROHO, Inc.
1501 S. 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® AirLITE® Cushion

General Description: AirLITE
Intended Use: The ROHO AirLITE Cushion (AirLITE) is a wheelchair support surface with a non-adjustable, air-filled, segmented-design, AIR FLOATATION Technology insert, encased in contoured foam. The AirLITE is intended to conform to an individual's seated shape to provide positioning. There is a weight limit of 300 lbs. (136kg), and the cushion must be properly sized to the individual. The AirLITE must be used with the supplied cover.

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

Cushion
AL1313HD
AL1315HD
AL1414HD
AL1416HD
AL1515HD
AL1517HD
AL1616HD
AL1618HD
AL1717HD
AL1718HD
AL1720HD
AL1816HD
AL1818HD
AL1820HD
AL1917HD
AL1919HD
AL2017HD
AL2018HD

Basic UDI: Cushion: 613732ALCTQ

SRN: SRN is not assigned. SRN will be assigned when EUDAMED is up and running.

Authorized representative: MDSS
Schiffgraben 41
30175 Hannover, Germany

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

Conformity procedure used: Annex IV EU DECLARATION OF CONFORMITY



Standards: Conformity to the general safety and performance requirements have been demonstrated by using the following standards:
EN 12182:2012
ISO 14971:2012 or 2019
EN ISO 13485:2016
EN ISO 10993-1
EN 1021-1 & -2
ISO 13732-1:2008
ISO 15223-1:2016
ISO 16840-6:2015
ISO 7176-16:2012
ISO16840 -2, -7 & -12

Original drawn up: 2020-11-11

Place and date: Belleville, Illinois, USA
2021-05-18

On behalf of ROHO, Inc.

5/18/21

Kurt Goomey
Vice President of Operations.