

## 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  
ALDEMO

**Basic UDI-DI:** Cushion: 613732ALCTQ

**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)

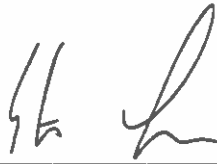
**Conformity procedure used:** EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III

**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 7176-16:2012  
ISO 16840 -2, -7 & -12

**Original drawn up:** 2020-11-11

**Place and date:** Belleville, Illinois, USA  
2025-01-03

On behalf of ROHO, Inc.



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Steven Louer  
Sr. Manager of Quality/Regulatory Compliance