

EU DECLARATION OF CONFORMITY

MANUFACTURER:



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The manufacturer declares under its own responsibility that the medical device

Product Name: BH 501 M
EMDN: 5302BH501M

Intended Purpose: The BH 501 M floor fastener is CE-marked and has been crash-tested in accordance with the requirements of DIN EN 1789 in conjunction with the utila carrying chairs from the ALS 118, ALS 128, ALS 318, ALS 328 and ALS 428 series. The floor mount is made of glass bead blasted stainless steel.

The floor mount is used to securely fasten the carrying chair in the vehicle. The utila carrying chair is equipped with two locking mushrooms for this purpose. The carrying chair is simply pushed into the floor mount until the floor mount lock audibly locks the locking mushroom. To release the carrying chair from the floor fastener, press in the red release handle and pull the carrying chair out of the floor fastener.

The integrated plastic guides prevent the locking mushrooms from grinding off unintentionally in the rail.

Device Classification: MD Class I

TESTED STANDARDS:

Quality management system - utila internal

GTIN / UDI-DI: 4262421215302

GMN / Basic UDI-DI: 4262421215302BH501MAT



The product is tested in accordance to DIN EN 1789 and complies with the essential requirements listed in the Regulation 2017/745 MDR directive on Medical Devices. In addition, the fastener complies with EN:2007+A2:2014 Sections 5.4 and 6.3.5 - Rescue service vehicles and their equipment - Ambulances and ECE / UN Regulation No. 17, Revision 04 to the 08 series of amendments - Uniform conditions for the approval of motor vehicles with regard to the seats, anchorages and headrests. All test in accordance with EN ISO/IEC 17025:2005 or EN ISO/IEC 17020:2012 by TÜV Rheinland in 02.2019 - technical document no. 195XS0028-00.



Troisdorf, Germany, January 2023

Sascha Ennenbach
Sascha Ennenbach M.D.