



Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

**ROHO, Inc.,
1501 South 74th St.
Belleville, IL 62223
USA**

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2021-09-08

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 475665

This certificate is subject to the following terms and conditions:

It is only valid for the device(s) listed hereafter;

It is not a proof for compliance to CE marking;

The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;

As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.

This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Certificate	BfArM Registration Number*
DOC-10440 Rev. D	Plastic Medical Cushions: ROHO® MOSAIC® Cushion; ROHO® Heavy Duty Cushion Cover	47477 62720	I	DOC-10755 signed 2021-04-09	N.A.	DE/CA09/0170/R08/017 DE/CA09/0170/R08/021
DOC-10480 Rev. D	Neoprene Medical Cushions: ROHO® HIGH PROFILE® Single Compartment Cushion; ROHO® HIGH PROFILE® Single Compartment Cushion with Sensor Ready™ Technology; ROHO® LOW PROFILE® Single Compartment Cushion Medical Cushion Cover: ROHO® Standard Cushion Cover; ROHO® Heavy Duty Cushion Cover	47477 62720	I	DOC-11727 signed 2021-04-09 DOC-11729 signed 2021-04-09	N.A.	DE/CA09/0170/R08/017 DE/CA09/0170/R08/021
DOC-10698 Rev. D	Neoprene Positioning Cushions: ROHO® CONTOUR SELECT® Cushion QUADTRO SELECT Cushion: ROHO® QUADTRO SELECT® HIGH PROFILE® Cushion; ROHO® QUADTRO SELECT® MID PROFILE™ Cushion; ROHO® QUADTRO SELECT® LOW PROFILE® ENHANCER Cushion: ROHO® ENHANCER® Cushion Medical Cushion Cover: ROHO® Standard Cushion Cover;	47477 62720	I	DOC-11733 signed 2021-04-13 DOC-11734 signed 2021-04-13 DOC-11730 signed 2021-03-05 DOC-11729 signed 2021-04-09	N.A.	DE/CA09/0170/R08/017 DE/CA09/0170/R08/021

	ROHO® Select Cushion Cover; ROHO® Heavy Duty Cushion Cover					
DOC-10802 Rev. C	Hybrid Elite Cushions: ROHO® Hybrid Elite® Dual Compartment Cushion; ROHO® Hybrid Elite SR™ Single Compartment Cushion; ROHO® Hybrid Elite® Cushion Cover Medical Cushion Cover: ROHO® Heavy Duty Cushion Cover	47477 62720	I	DOC-11735 signed 2021-04-09 DOC-11729 signed 2021-04-09	N.A.	DE/CA09/0170/R08/017 DE/CA09/0170/R08/021
DOC-10803 Rev. A	Neoprene Mattress Overlay: ROHO® DRY FLOATATION® Mattress Overlay System; ROHO® DRY FLOATATION® Bariatric Mattress Overlay System Reusable Mattress Cover, Reusable Bariatric Mattress Cover: ROHO® Reusable Mattress Overlay System Cover; ROHO® Reusable Mattress Overlay Bariatric System Cover	47455 47476	I	DOC-12229 signed 2020-12-11 DOC-12235 signed 2020-12-11	N.A.	DE/CA09/0170/R08/018 DE/CA09/0170/R08/020
DOC-11739 Rev. B	Plastic Mattress Overlays: ROHO® PRODIGY® Mattress Overlay System	47455 47476	I	DOC-12281 signed 2021-01-06	N.A.	DE/CA09/0170/R08/018 DE/CA09/0170/R08/020
DOC-11739 Rev. B	Reusable Mattress Cover, Reusable Bariatric Mattress Cover: ROHO® Reusable Mattress Overlay System Cover	47455 47476	I	DOC-12235 signed 2020-12-11	N.A.	DE/CA09/0170/R08/018 DE/CA09/0170/R08/020
DOC-12034 Rev. A	AirLITE: ROHO® AirLITE® Cushion	11100	I	DOC-12300 signed 2021-01-08	N.A.	DE/CA09/0170/R08/017
DOC-12240 Rev. A	Agility: ROHO® AGILITY® Max Contour Back Support; ROHO® AGILITY® Back Support Quick Release Hardware; ROHO® AGILITY® Back Support Direct Mount Hardware; ROHO® AGILITY® UniTrack Rail	36254 37744 64619	I	DOC-12368 signed 2021-01-15	N.A.	DE/CA09/0170/R08/022

DOC-12844 Rev. – (initial release)	ROHO® Hybrid Select Cushion	47477	I	DOC-13569 signed 2021-08-25	N.A.	DE/CA09/00180904
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*The registration number has been issued by the German Competent Authority.