

Test Verification of Conformity

Verification Number: 2201715STO-VOC

On the basis of the tests undertaken, the sample of the below product have been found to comply with the requirements of the referenced standard at the time the tests were carried out. This verification is part of the full test reports and should be read in conjunction with them. This verification replaces previous verification number 2101487STO-VOC dated: 24-Aug-2021

Applicant Name & Address: Human Care HC Sweden AB

Årstaängsvägen 21B

SE-117 43 Stockholm, Sweden

Product Description: Stationary hoist, fixed to building (ceiling)

Ratings & Principle Internal battery, 24 VDC, 2.3 Ah, Type B, IPX4

Characteristics: Duty cycle 15:85 (max 2 min. continuous operation)

Max load: 150kg or 220kg or 300kg. Hand control IPX5

PSU: 100-240 VAC, 1.6A, 50-60Hz, Class I

Output: 27.8VDC, 0.8A

Models/Type References: AltaiR, HeliQ and Roomer S

Brand Names:

Specification<s>/Standards: IEC 60601-1:2005

ISO 10535:2006

Verification Issuing Office Name

& Address:

Intertek Semko AB

Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden

Date of Tests: 2014-01-30 to 2015-01-12

2015-11-30 - 2015-12-04 2016-05-23 - 2016-05-26 2023-04-30 - 2023-10-16

Test Report Number(s): 1618959STO-002, 2101487STO-001, 2201715STO-001

and 1520257STO-001

Additional information in Appendix.

Signature

Name: Natalia Pyatanova Position: Manager Medical

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Date: 26 Oct 2023

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APPENDIX: Test Verification of Conformity

This is an Appendix to Test Verification of Conformity Number: 2201715STO-VOC

Manufacture Name & Address:

Same as applicant

The product is in conformity with the following standards:

- IEC 60601-1-2 as shown in Intertek test reports No. 1315129-1 and 1412663-1

- CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 as shown in Intertek test report 1618959STO-002.

- CAN/CSA-Z10535-03 as shown in Intertek test report 1520257-003.

Only requirements in IEC 60601-1:2005, as pointed out by Intertek test report ISO 10535:2006, including electrical safety and mechanical safety (shearing, crushing), have been evaluated.

Rail systems, body support and accessories such as sling bars, slings, stretchers, scales have not been evaluated by Intertek Semko AB. Biocompatibility according to EN ISO 10993 has not been evaluated by Intertek Semko AB.

Model differences:

AltaiR: has the lifting belt fixed to the rail system so that the entire hoist is raised and lowered.

HeliQ: is fixed to the rail system only the hoists spreader bar is raised and lowered. Can be equipped with a transfer motor and charged continuously through the rails and is then called HeliQ PT.

Roomer S: has the lifting belt fixed to the rail system so that the entire hoist is raised and lowered. Roomer S has also two lifting belts which are used simultaneously when transferring from room to room and some additional mechanical parts used for switching between the belts.

Signature

Name: Natalia Pyatanova Position: Manager Medical

Date: 26 Oct 2023



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