

EC Declaration of Conformity



Manufacturer Name: HelpSoq B.V.
Manufacturer Address: Hondiusstraat 28C
6827DE Arnhem
The Netherlands



SRN : NL-MF-000044715
Basic UDI-DI : 8720865049HS018C

Name of the product: **HelpSoq ON**



Intended purpose: an electric aid for donning Therapeutic Elastic Stockings (TEK)

HelpSoq B.V. does hereby declare that the above mentioned product meets the essential health and safety requirements and is in conformance with the provisions of the MDR Regulation (EU) 2017/745 on medical devices, and is classified as a Class I medical device.

Applied standards:

Reference IEC	Title
EN60335-1:2012 + A1:2019 + A2:2019	Household and similar electric appliances – Safety Part 1: General requirements
EN55014-1	Electromagnetic compatibility EMC – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission
EN55014-2	Electromagnetic compatibility EMC – Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity

The above mentioned product meets the relevant provisions of Directives:

- LVD 2014/35/EU
- EMC 2014/30/EU
- RoHS 2011/65 EU

The above mentioned product is also produced under a quality scheme at least in conformity with ISO 9001:2015 requirements.

This Declaration of Conformity is issued under the sole responsibility of HelpSoq B.V.

Date: 1/Nov/2024

Harpert Wouters (Head R&D)
Arnhem, NL