EU Declaration of Conformity

from company Evomotion GmbH for the evomove®

This product is a medical device in accordance with Article 2 of the MDR.

Manufacturer	Evomotion GmbH
Manufacturer address	Wallstraße 3, D-21335 Lüneburg
SRN	DE-MF-000005900
Product name	evomove®
Basic-UDI-DI	42519214evomoveA8
Classification according to MDR Annex VIII	class IIa (Rule 9)
Intended use	The evomove® is a product that electronically stimulates muscles (nerves) during walking. It serves as a tool for patients with deficits/pathologies in their gait and is designed for the connection with an orthesis or suitable cuff. In case the orthesis is not the carrier, the cuff is. By means of the integrated sensor technology significant moments in gait can be detected and calculated. Derived from this, a temporally defined contraction of muscles that are relevant for gait can ensue. A medical app allows the expert to configure, the patient to control the device. The target group consists of patients with gait restrictions due to lack of nervous control (e.g. due to a central nervous disorder like stroke).
Guidelines	2017/745/EU (MDR) 2011/65/EU (RoHS) 2014/53/EU (RED)
Applied norms and standards (CS)	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 10993-1:2020 EN 60601-1:2006 EN 60601-1-2:2015 EN 60601-1-11:2015 EN 60601-2-10:2015 EN 62304:2006 EN 62366-1:2015
Conformity assessment procedure	MDR annex IX
Notified body	TÜV SÜD Product Service GmbH (0123)

We declare under our sole responsibility that the listed medical device complies with all requirements of Regulation (EU) 2017/745 on medical devices and other applicable EU legislation requiring a declaration of conformity.

The declaration is valid from the date of signature until March 05.2029.

Aljoscha Diercks, CEO, Lüneburg, March 03.2024