

EU Declaration of Conformity

D-P002-51-56-09

Manufacturer:

mo-Vis bv



Address:

Biebuyckstraat 15 D
B-9850 Deinze
Belgium

Hereby we declare that mo-Vis bvba, as a legal manufacturer, has the exclusive responsibility to draw up this Declaration of Conformity.

This declaration concerns the **Micro Joystick Omni (P002-51)**, **Micro Joystick R-net (P002-52)**, **Micro Joystick LiNX (P002-54)** and **Micro Joystick Omni (5gr adapted) (P002-55)**, which are very small proportional joysticks intended to support people with very poor muscle strength and/or limited movements in controlling or manoeuvring a powered wheelchair.

They are **Medical Devices Class I**, with reference to rules 1 and 13 of the Annex VIII of the Medical Device Regulations 2017/745.

mo-Vis declares that these products are in conformity with the essential requirements and provisions of the Medical Device Regulations 2017/745, Annex I and with the Medical Device Regulations 2017/745, Annex IV.

The software in this device (Class B) is developed according to IEC 62304:2006 +A1:2015 Medical Device Software Development.

UDI: 540700832MICROJSED

This Declaration of Conformity is valid for all devices described here above and until the issue of a revised Declaration of Conformity after change of the product.

Rebecca Van Craeymeersch
mo-Vis bv
Quality Manager

mo-Vis bv

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