

EU Declaration of Conformity

D-P002-71-56-05

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 following products:

All-Round Joystick Omni (P002-71), All-Round Joystick Light Omni (P002-72), All-Round Joystick R-net (P002-75) and All-Round Joystick Light R-net (P002-76)

which are multifunctional operable joysticks intended to support people with reduced muscle strength in controlling or manoeuvring a powered wheelchair.

They are **Medical Devices Class I**, with reference to rule 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: 540700832ALLRJS4K

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.

A handwritten signature in black ink, appearing to read 'Rebecca Van Craeymeersch', with a long horizontal flourish extending to the right.

Deinze, 30/04/2021

Rebecca Van Craeymeersch
mo-Vis bv
Quality Manager

mo-Vis bv

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