permobil

To whom it may concern,

2021-03-10

MDR Statement for Supplier evaluation of Permobil under MDR 2017/745

As a manufacturer and supplier of medical devices under the European legislation MDR 2017/745, Permobil issues the following statement regarding our MDR status.
This statement is intended to be used by our Economical operator (EO) for the purpose of verifying the status of Permobil products and systems in relation to the MDR 2017/745.

Permobil is a manufacturer and supplier of Medical Devices (as defined in MDR 2017/745), accessories, spare parts and services of Medical Devices. Permobil does not supply invitro diagnostic products, nor does Permobil supply medical products under any other European legislation.

In general, Permobil products comply with the MDR 2017/745. There are some exceptions of legacy products that are still valid under the MDD 93/45/EC. Permobil can upon request provide the necessary documentation including valid Declarations of Conformity for the products in question.

Permobil manufacturing facilities for power wheelchairs as well as the facilities in the Permobil subsidiaries ROHO and TiLite are ISO 13485:2016 certified and certificates are available upon request.

All Permobil products are traceable by a unique serial number in case of the need for Field Safety Corrective Actions (as defined in the MDR). Permobil requires all its EO to ensure traceability through the distribution chain. Permobil will ensure its EO are adequately notified in case of a recall or non-conformity, in accordance with the vigilance requirements under the MDR.

Permobil confirms that a product identification number (Unique Device Identification, UDI) compliant with the MDR will be affixed, at each of our products at the latest when that is legally required for Class I products in EU.

Your sincerely,

Anna-Karin Wahlström
Director of compliance MDD/MDR
Permobil