EC DECLARATION OF CONFORMITY

PRODUCT CATEGORY: Orthotic Devices & Assistive Dynamic arm support system

PRODUCTS: Product families:

SaeboGlove

GMDN: 41457

BUDIDI/GMN: 0850331006SaeboGloveX5

SaeboFlex

GMDN: 41457

BUDIDI/GMN: 0850331006SaeboFlexPH

SaeboReach

GMDN: 41053

BUDIDI/GMN: 0850331006SaeboReachVL

SaeboStretch

GMDN: 41459

BUDIDI/GMN: 0850331006SaeboStretchFE

SaeboStep

GMDN: 36206

BUDIDI/GMN: 0850331006SaeboStepT4

SaeboMAS

GMDN: 48071

BUDIDI/GMN: 0850331006SaeboMASLL

SaeboMASmini

GMDN: 48071

BUDIDI/GMN: 081001835SaeboMASminiB7

CLASSIFICATION: Classified as **Class I self-declaration,** by applying **Rule No. 01** of Annex VIII of the Medical Devices Regulation (MDR 2017/745)

SRN REF: IE-AR-000003999

CONFORMITY ASSESSMENT ROUTE:

MDR 2017/745, Annex V – Self Declaration, Annex II, III - Generation and Maintenance of this Technical File to demonstrate compliance with the relevant General Safety & Performance Requirements (GSPR) of MDR 2017/745 - Annex I.

Saebo Inc. hereby declares that the product has correct packaging and the relevant information and instructions required for use of the products. All manufacturing activities are subjected to the appropriate methods of internal quality control and inspection. We declare that the above mentioned products meet the provisions of Medical Device Regulation MDR 2017/745 relating to medical devices and is classified in that field as a **Class I non-invasive, non-sterile self-declaration medical device.**

All supporting documentation is retained at the premises of the OEM Manufacturer. Saebo Inc's Quality System and Technical Documentation is **not** subject to Notified Body surveillance; however, our devices **are** registered as Class I self-declaration products with the UK MHRA.

NOTIFIED BODY: Not Applicable (Class I Medical Devices)

MANUFACTURER: Saebo Inc., 2549 Wilkinson Blvd
Suite 120-B, Charlotte
NC 28208
USA

EU REPRESENTATIVE: European Healthcare and Device Solutions Ltd
Stratton House, Bishopstown Road, Cork
T12 Y9TC
Ireland

UK RESPONSIBLE PERSON: European Device Solutions Ltd
15 Coanwood Drive, Whitley Bay, Tyne & Wear
NE25 9GB
United Kingdom

Approval: Glyn Blakey – Managing Director

Date: 6th December 2022