

EU Declaration of Conformity

Legal manufacturer	Merrithew International Inc.
SRN Number	CA-MF-000005225
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European Authorized Representative (EC REP)	S4M EUROPE 59, rue Castellion 01100 Oyonnax - France

We, Merrithew International Inc., declare under our sole responsibility that the following products (listed in annex I) are designed, manufactured and distributed according to our Quality Management System that conforms to ISO 13485:2016 standard, as well as to other standards or regulatory documents as mentioned in the Technical Documentation Rev 01;

Applicable models as listed in Annex I	Basic UDI-DI
Reformer	690650REFORMERKA
Vertical Frame	690650VERTICALFRAME3M
Reformer & Vertical Frame	690650REFORMERVERTFRAMEYZ

The declaration is in conformity with the relevant Medical Device Regulation (EU) 2017/745 (MDR). The product is in Class I, according to annex VIII, rule 1 of the MDR.

This EU Declaration of Conformity is valid until: **December 31, 2027**

Annex I: Products included in this EU Declaration of Conformity

Device name	Device description (intended purpose)	Product code (model)	UDI-DI
Reformers	Reformers used as part of Pilates exercise during rehabilitation	ST-01071	00690650010711
		ST-01073	00690650010735
		ST-01077	00690650010773
		ST-01080	00690650010803
		ST-01082	00690650010827
		ST-01084	00690650010841
		ST-11032	00690650110329
		ST-11049	00690650110497
		ST-11054	00690650110541
		ST-11068	00690650110688
		ST-11076	00690650110763
		ST-11078	00690650110787
		ST-11080	00690650110800
		ST-02094	00690650020949
		ST-02096	00690650020963
ST-02098	00690650020987		
Vertical Frames	Vertical Frames used as part of Pilates exercise during rehabilitation	ST-02039	00690650020390
		ST-02045	00690650020451
		ST-02047	00690650020475
		ST-02076	00690650020765

Reformer & Vertical Frame	Reformers & vertical frames used as part of Pilates exercise during rehabilitation	ST-01067	00690650010674
		ST-01069	00690650010698
		ST-01076	00690650010766
		ST-01081	00690650010810
		ST-01083	00690650010834
		ST-01085	00690650010858
		ST-11001	00690650110015
		ST-11050	00690650110503
		ST-11079	00690650110794

Signed for and on behalf of Merrithew International Inc.;

Place of issue	Date	Name	Function	Signature
Toronto, Canada	February 11, 2022	Lindsay Merrithew	President & CEO	