

Declaration of Conformity

Reference Document: EU Medical Device Regulation (MDR) Classification Assessment

Manufacturer's Name: CaliberMRI, Inc.

United States Address: 4909 Nautilus Court North, Suite 121, Boulder, Colorado 80301

CaliberMRI's products are manufactured in the United States of America and freely sold in the USA. CaliberMRI declares under our sole responsibility that the following products conform to MDR 2017/745:

SRN#	Product Name	Model #	Product Classification	Year of Manufacture	Classification
TBD	Essential System Phantom	106	Accessory to a medical device	2021	Class I, Rule 1
TBD	Essential Breast Phantom	107	Accessory to a medical device	2021	Class I, Rule 1
TBD	Essential Prostate Phantom	108	Accessory to a medical device	2021	Class I, Rule 1
TBD	Diffusion Phantom	128	Accessory to a medical device	2014	Class I, Rule 1
TBD	System Phantom Lite	129	Accessory to a medical device	2018	Class I, Rule 1
TBD	Premium System Phantom	130	Accessory to a medical device	2014	Class I, Rule 1
TBD	Premium Breast Phantom	207	Accessory to a medical device	2016	Class I, Rule 1
TBD	Premium Prostate Phantom	132	Accessory to a medical device	2017	Class I, Rule 1

Name

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Signed

Title: CaliberMRI Sales and Marketing Manager, Operations Support

Date: 9/20/2021