



EU Declaration of Conformity

Statement of Use: Verify status before each use

This declaration is issued under the sole responsibility of MMJ Labs, LLC dba Pain Care Labs.

We, the manufacturer hereby declare that the below-mentioned medical device complies with the relevant provisions of the European Communities' Council Regulation 2017/745/EC in accordance with Annex I, General Safety and Performance Requirements and Annex IX. This declaration is supported by the Quality Management System being in compliance with 2017/745/EC.

All supporting documentation is retained at the premises of the manufacturer.

Manufacturer	MMJ Labs, LLC dba Pain Care Labs 195 Arizona Ave LW0 30307 Atlanta, USA
Product Name	Buzzy® and VibraCool®
Product Trade Name	Buzzy® and VibraCool®
Product Code	Reference schedule
Product Family	Buzzy® and VibraCool®
Intended Purpose	Therapeutic Massager combined with Cold Pack used to relieve minor aches and pains.
SRN (Single Registration Number)	US-MF-000010505
Basic UDI-DI	85692100BuzzyC2
GMDN Code	36560 37240
Risk Classification	Class 1 (active, non-measuring, non-sterile) Annex VIII of regulation 2017/745, Rule 13
Sterilization Method	Non-sterile
Conformity Assessment	Article 52, section 7 of the Medical Device Regulation 2017/745/EC Technical Documentation: Annex II and Annex III of regulation 2017/745
Excluded Sections	None
Common Specifications	None




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<p>Standards</p>	<ul style="list-style-type: none"> • EN 1041:2008 (Harmonized Version) • EN ISO 10993-1:2009/AC:2010 (Harmonized Version) • BS EN ISO 10993-1:2020 • ISO 10993-1: 2018 • EN ISO 10993-5:2009 (Harmonized Version) • EN ISO 10993-10:2013 • EN ISO 15223-1:2012 (Harmonized Version) • ISO 15223-1:2016 • ISO 15223-2:2010 • EN ISO 14971:2012 (Harmonized Version) • ISO 14971:2019 • ASTM F1980-16 • MEDDEV 2.7.1
<p>Authorised Representative</p>	<p>CS Lifesciences Europe Limited The Black Church St. Mary's Place Dublin 7 D07 P4AX Ireland</p> <p>Email: eurep@cslifesciences.com</p>
<p>Notified Body for CE Mark</p>	<p>Not Applicable</p>
<p>EC Certificate for CE Mark</p>	<p>Not Applicable</p>
<p>Quality System Certificate</p>	<p>Not Applicable</p>

Approved on behalf of MMJ Labs, LLC dba Pain Care Labs

<p>Amy Baxter CEO</p>	<p>Amy Baxter MD</p> 
<p>Date, town, and country of signing</p>	<p>September 13th, 2022, Atlanta, United States of America</p>

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Schedule: Product Codes/ Catalogue Numbers

Product Code/Catalogue Number	Description and Size
BTH 1	BUZZY HEALTHCARE BEE STRIPED
BTH 2	BUZZY HEALTHCARE PLAIN BLACK
BTH 3	BUZZY HEALTHCARE LADYBUZZ®
BKHM1	Buzzy® Mini Healthcare Striped
BKHM2	Buzzy® Mini Healthcare Plain Black
BKHM3	Buzzy® Mini Healthcare LadyBuzzy®
BKP	BUZZY PRO

Product Code/Catalogue Number	Description and Size
BKT1	BUZZY PERSONAL STRIPED
BKT2	BUZZY PERSONAL PLAIN BLACK
BKT3	BUZZY PERSONAL LADYBUZZ®
BKM1	Buzzy® Mini Personal Striped
BKM2	Buzzy® Mini Personal Plain Black
BKM3	Buzzy® Mini Personal LadyBuzzy®

Product Code/Catalogue Number	Description and Size
VC-Plantar	VIBRACOOOL® FOR PLANTAR FASCIITIS, GOUT
VC-2	VIBRACOOOL® FLEX
VC-E	VIBRACOOOL® WRIST/ELBOW "EASY FIT"
VC-K	VIBRACOOOL® KNEE/HEADACHE "EXTENDED FIT"
VCP-DME	VIBRACOOOL® PRO DME
VCP-UE	VIBRACOOOL® PRO UPPER EXTREMITY
VCP-LE	VIBRACOOOL® PRO LOWER EXTREMITY
VCP-200H	VIBRACOOOL® PRO HEALTHCARE