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.

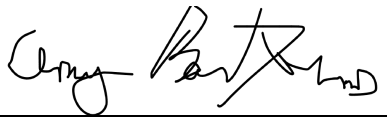
Manufacturer	MMJ Labs, LLC dba Pain Care Labs 195 Arizona Ave LW0 30307 Atlanta, USA
Product Name	Buzzy® and VibraCool®
Product Trade Name	Buzzy® and VibraCool®
Product Code	Reference schedule
Product Family	Buzzy® and VibraCool®
Intended Purpose	Therapeutic Massager combined with Cold Pack used to relieve 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 EMC Directive 2014/30/EU We hereby declare that our products comply with Directive 2011/65/EU (RoHS 2), as amended by Directive (EU) 2015/863 (RoHS 3), on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Excluded Sections	None
Common Specifications	None

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Standards	• 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
Authorised Representative	CS Lifesciences Europe Limited The Black Church St. Mary's Place Dublin 7 D07 P4AX Ireland Email: eurep@cslifesciences.com
Notified Body for CE Mark	Not Applicable
EC Certificate for CE Mark	Not Applicable
Quality System Certificate	Not Applicable

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

Amy Baxter **CEO**	Amy Baxter MD 
Date, town, and country of signing	**August 4, 2025, Atlanta, United States of America**

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Schedule: Product Codes/ Catalogue Numbers

Product Code/Catalogue Number	Description and Size
BTH 1	BUZZY® XL HEALTHCARE BEE STRIPED
BTH 2	BUZZY® XL HEALTHCARE PLAIN BLACK
BTH 3	BUZZY XL HEALTHCARE LADYBUZZ®
BTH4	BUZZY® XL HEALTHCARE ROYALBUZZ®
BKHM1	Buzzy® Mini Healthcare Striped
BKHM2	Buzzy® Mini Healthcare Plain Black
BKHM3	Buzzy® Mini Healthcare LadyBuzz®
BZP	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 LadyBuzz®

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