

## 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.

<b>Manufacturer</b>	MMJ Labs, LLC dba Pain Care Labs 195 Arizona Ave LW0 30307 Atlanta, USA
<b>Product Name</b>	VibraCool® Ice Packs, Universal Healthcare Ice Wings, Universal Soft Ice Wings
<b>Product Trade Name</b>	VibraCool® Ice Packs, Buzzy® Universal Healthcare Ice Wings, Buzzy® Universal Soft Ice Wings
<b>Product Code</b>	Reference schedule
<b>Product Family</b>	VibraCool®
<b>Intended Purpose</b>	Cold pads for pain relief
<b>SRN (Single Registration Number)</b>	US-MF-000010505
<b>Basic UDI-DI</b>	85692100VibraCoolJF
<b>GMDN Code</b>	37240
<b>Risk Classification</b>	Class 1 (Non active, non-measuring, non-sterile) Annex VIII of regulation 2017/745, Rule 1
<b>Sterilization Method</b>	Non-sterile
<b>Conformity Assessment</b>	Article 52, section 7 of the Medical Device Regulation 2017/745/EC Technical Documentation: Annex II and Annex III of regulation 2017/745
<b>Excluded Sections</b>	None
<b>Common Specifications</b>	None




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

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

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



**PainCareLabs™**  
BUZZY® PAIN SOLUTIONS

**MMJ Labs, LLC dba Pain Care Labs**

**Revision:** 02

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**Approved Date:** 13<sup>th</sup> Sept 22

**Reference:** 2021-2

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**Schedule: Product Codes/ Catalogue Numbers**

Product Code/Catalogue Number	Description and Size
<b>VC-ICE</b>	VIBRACOOOL® ICE PACKS
<b>REP-MBG25</b>	UNIVERSAL HEALTHCARE ICE WINGS 25 PACK
<b>REP-MS100</b>	UNIVERSAL SOFT ICE WINGS 100 PACK