# 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.

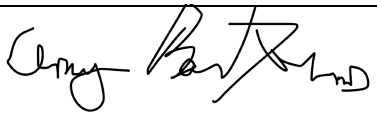
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|---|---|
| **Manufacturer** | MMJ Labs, LLC dba Pain Care Labs<br>195 Arizona Ave LW0 30307 Atlanta, USA |
| **Product Name** | VibraCool® Ice Packs, Universal Healthcare Ice Wings, Universal Soft Ice Wings |
| **Product Trade Name** | VibraCool®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

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| **Standards** | • EN 1041:2008 (Harmonized Version)<br>• EN ISO 10993-1:2009/AC:2010 (Harmonized Version)<br>• BS EN ISO 10993-1:2020<br>• ISO 10993-1: 2018<br>• EN ISO 10993-5:2009 (Harmonized Version)<br>• EN ISO 10993-10:2013<br>• EN ISO 15223-1:2012 (Harmonized Version)<br>• ISO 15223-1:2016<br>• ISO 15223-2:2010<br>• EN ISO 14971:2012 (Harmonized Version)<br>• ISO 14971:2019<br>• ASTM F1980-16<br>• MEDDEV 2.7.1 |
| **Authorised Representative** | CS Lifesciences Europe Limited<br>The Black Church<br>St. Mary's Place<br>Dublin 7<br>D07 P4AX<br>Ireland<br><br>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

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|---|---|
| **Amy Baxter**<br>**CEO** | Amy Baxter MD  |
| **Date, town, and country of signing** | **January 2, 2025, Atlanta, United States of America** |

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**Schedule: Product Codes/ Catalogue Numbers**

| Product Code/Catalogue Number | Description and Size |
|---|---|
| **VC-ICE** | VIBRACOOL® ICE PACKS |
| **REP-MBG25** | UNIVERSAL HEALTHCARE ICE WINGS 25 PACK |
| **REP-MS100** | UNIVERSAL SOFT ICE WINGS 100 PACK |
| **REP-MBG50** | UNIVERSAL HEALTHCARE ICE WINGS 50 PACK |
| **REP-SP10** | SINGLE PATIENT ICE PACKS - PRO/PLANTAR 10 PACK |
| **REP-SP100** | SINGLE PATIENT ICE PACKS - PRO/PLANTAR 100 PACK |