1) **Manufacturer: HYPERICE, INC.**

Address: **525 Technology Dr. | Suite 100, Irvine, California 92618, USA**

2) **European authorized representative:** CEpartner4U BV

Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS
SRN: NL-AR-000000111

3) Product(s):

Product name	Trade Name	Catalogue number	Intended Purpose	Risk class / rule[1]	Basic UDI-DI[2]	First date of CE-compliance
Ice Compression Device Back	Hyperice	10040	External Ice Wrap	Risk Class I / Rule 1	10010 001-00	2015-07-22
Ice Compression Device Knee	Hyperice	10010	External Ice Wrap	Risk Class I / Rule 1	10110 040-00	2015-07-22
Ice Compression Device Shoulder Left	Hyperice	10021	External Ice Wrap	Risk Class I / Rule 1	10210 001-00	2015-07-22
Ice Compression Device Shoulder Right	Hyperice	10022	External Ice Wrap	Risk Class I / Rule 1	10220 001-00	2015-07-22
Ice Compression Device Extended Shoulder Left	Hyperice	10051	External Ice Wrap	Risk Class I / Rule 1	10130 040-00	2015-07-22
Ice Compression Device Extended Shoulder Right	Hyperice	10052	External Ice Wrap	Risk Class I / Rule 1	10030 001-00	2015-07-22
Ice Compression Device Utility	Hyperice	10030	External Ice Wrap	Risk Class I / Rule 1	10030 001-00	2015-07-22
Fuel Cell	Hyperice	20010	External Ice Wrap	Risk Class I / Rule 1	10010 001-00	2015-07-22

4) The product(s) described above is in conformity with:

Title	Document No.
Medical Device Regulation	(EU) 2017/745
RoHS Directive	2011/65/EU

[1] See risk classification in Medical Device Regulation, annex VIII
[2] Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI

5) **<u>Additional information</u>** *(conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure: Medical Device Regulation, Annex IV of Regulation 2017/745/EU

Class I Device

Registration nr.: NL-CA002-2015-35755

In conformity with following Common Specification(s):

-

These Products are fully compliant and do not contain the restricted substances above levels noted in EU Directive 2011/65/EU.

This declaration of Conformity is issued under the sole responsibility of the manufacturer:

Scott Lambert

Manager, Quality & Regulatory Systems

Hyperice, Inc.

2024-04-01