

## EU DECLARATION OF CONFORMITY

No. 09/2022

is issued under the sole responsibility of the manufacturer

in compliance with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, as amended.

Manufacturer declares that the medical device stated below fulfills the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Manufacturer:	AVEFLOR, a.s.
Single Registration Number (SRN):	CZ-MF-000003103
VAT reg. No.:	CZ64259838
Registered place of business:	Budceves 26, 507 32 Kopidlno, Czech Republic
Manufacturing site:	Budceves 26, 507 32 Kopidlno, Czech Republic
Authorised representative:	IVF HARTMANN AG, Victor-von-Brunns-Strasse 28, 8212 Neuhausen, Switzerland

Product name:	<b>Trioderm® CARE Chladicí sprej</b>
Product code:	<b>Z38, SZ85, SZ90</b>
Product trademark:	Trioderm®
Basic UDI-DI:	859401370Z38NT
EAN:	Z380000      8594013704694 SZ850000      20188375 SZ900000      4036581531486

Full list of the EAN codes of language variants of product is included in Technical File

Brand names: listed in the Annex

Models: 200 ml of product in aerosol can of 270 ml-volume  
60 ml of product in aerosol can of 80 ml-volume

Intended purpose: Temporary relief of pain of muscle contusion, joint sprains, muscle spasms and other injuries due to impact, fall or increased sports load; and relief of pain during minor procedures such as venipuncture before inserting a cannula or catheter into a vein.

### AVEFLOR, a.s.

Production and sale of cosmetics, medical devices and veterinary products  
Budčeves 26, 507 32, Kopidlno, Company Reg.No.: 64259838, Taxpayer Reg. No.: CZ64259838  
Tel.: +420 493 551 111, Fax: +420 493 551 112, e-mail: [aveflor@aveflor.cz](mailto:aveflor@aveflor.cz)

Product classification: non-invasive, inactive, non-implantable, non-sterile medical device without measuring function, for transient term use

Product classification acc. to Regulation (EU) 2017/745 European Parliament and of the Council on medical devices, Annex VIII:

**risk class I, Rule I**

Assessment of the conformity acc. to Regulation (EU) 2017/745 European Parliament and of the Council on medical devices, Chapter IV, Section 2, Article 52, point 7.

Product composition: BUTANE, PROPANE, ISOBUTANE

**Trioderm® CARE Chladicí sprej** is in compliance with the provisions of following legal regulations and standards of European Union as amended:

- Regulation (EU) 2017/745 European Parliament and of the Council on medical devices
- Council Directive 75/324/EEC as amended, on the approximation of the laws of the Member States relating to aerosol dispensers;
- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- EN ISO 10993 Biological evaluation of medical devices;
- EN ISO 10993-1:2021 - Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2013 - Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-18:2020 - Part 18: Chemical characterization of medical device materials within a risk management process
- ČSN EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

and also in compliance with the technical documentation of manufacturer:

- bulk and final product specification;
- specification of packaging materials and binding pattern of used packaging and labels;
- testing methods of bulk and final products;
- bill of material of bulk and final product;
- manufacturing prescription including the packaging operations;
- Risk analysis;
- Protocol on Biosafety evaluation;
- Clinical Evaluation Report.

In behalf of the company AVEFLOR, a.s., at Budceves, 2nd<sup>th</sup> November 2022



**AVEFLOR, a.s.**  
**Úsek jakosti**

Ing. Lucie Šotková  
Qualified person of AVEFLOR, a.s.

**AVEFLOR, a.s.**

Production and sale of cosmetics, medical devices and veterinary products  
Budceves 26, 507 32, Kopidlno, Company Reg.No.: 64259838, Taxpayer Reg. No.: CZ64259838  
Tel.: +420 493 551 111, Fax: +420 493 551 112, e-mail: [aveflor@aveflor.cz](mailto:aveflor@aveflor.cz)

Annex: **Brand names**

**Trioderm® CARE Chladicí sprej**

Sensomed® Kälte-Spray

sensiplast® Kältespray

sensiplast® COOLING SPRAY/Kylsprej/Kylmäsuihke

sensiplast® Spray Frío

sensiplast® COOLING SPRAY

SOS Sport-Eis-Spray

SPOPHY COOLANT SPRAY

DermaPlast® ACTIVE Ice Spray

Trioderm® CARE Cooling spray

All products of the above stated brand names are identical to Trioderm® CARE Chladicí sprej.

**AVEFLOR, a.s.**

Production and sale of cosmetics, medical devices and veterinary products  
Budčeves 26, 507 32, Kopidlno, Company Reg.No.: 64259838, Taxpayer Reg. No.: CZ64259838  
Tel.: +420 493 551 111, Fax: +420 493 551 112, e-mail: [aveflor@aveflor.cz](mailto:aveflor@aveflor.cz)