



Milan, 15 December 2023

CL/0716/23/GL/vc

To: TOSVAR SRL
Via del Lavoro, 10
20060 Pozzo d'Adda (MI)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate n°27212 – **Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (number 4380429) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer for the devices in Table n. 1:

TOSVAR SRL
Via del Lavoro, 10
20060 Pozzo d'Adda (MI)
Italia

Table n.1

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	Device name under MDD corresponding to the device under MDR application	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
Ghiaccio spray	Ila	Ghiaccio spray	Certificate n. 27212 – issued on 12/07/2019 by CERTIQUALITY S.r.l. (NB 0546)

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

- The above-mentioned agreement (n. 4380429) was signed before the expiry date (2024/05/26) of the certificates shown in table n.1;
- Bureau Veritas Italia Spa is not responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1



**BUREAU
VERITAS**

As required by EU Regulation 2023/607, the validity of the MDD certificate n° 27212 is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2023/12/15	0	Initial issue

GIORGIO LANZAFAME
Bureau Veritas Italia S.p.A.
Certification Division
LOCAL TECHNICAL
MANAGER