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DICHIARAZIONE DI CONFORMITA'



Il fabbricante:

Ragione sociale: DISPOTECH SRL
Sede: GORDONA (SO)- VIA AL PIANO, 29
Cod. fiscale/Part.IVA: 00672170149
R.E.A.: 47213

DICHIARA che il prodotto: GHIACCIO Istantaneo

è conforme ai requisiti essenziali del Dgs.46/1997 che recepisce la Direttiva Dispositivi Medici 93/42/CEE e s.m.i. compresa la direttiva 2007/47/CE recepita con D.lgs. 37/2010

Classe del dispositivo: IIa allegato IX regola 9

In rispondenza a quanto stabilito dalle norme armonizzate:

Decreto Legislativo 24.02.1997, n.46 - Attuazione della direttiva 93/42/CEE, concernente i dispositivi medici
MDD 93/42/CEE e successive modifiche integrative (es.: Direttiva Europea 2007/47/CE) - Direttiva dispositivi medici
REGOLAMENTO (UE) 2023/607 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 15 marzo 2023 che modifica i regolamenti (UE) 2017/745 e (UE) 2017/746 per quanto riguarda le disposizioni transitorie per determinati dispositivi medici e dispositivi medico-diagnostici in vitro

MEDDEV 2.12-1 rev.8 Linee guida sul sistema di vigilanza dei dispositivi medici

UNI EN ISO 13485 :2016 Dispositivi medici – Sistemi di gestione della qualità – Requisiti per scopi regolamentari

UNI CEI EN ISO 15223-1:2017 Simboli da utilizzare nelle etichette del dispositivo medico, nell' etichettatura e nelle informazioni che devono essere fornite – parte I requisiti generali

UNI CEI EN ISO 14971:2020 Applicazione della gestione dei rischi ai dispositivi medici

UNI CEI EN 1041:2013 Informazioni fornite dal fabbricante di dispositivi medici

ISO 10993-1:2018 Valutazione biologica dei dispositivi medici

MEDDEV 2.7.1 Linee guida sulla valutazione clinica dei dispositivi medici

Reg. CE N, 1907/2006 concernente la registrazione, la valutazione, l'autorizzazione e la restrizione delle sostanze chimiche (REACH).

REGOLAMENTO (CE) N. 552/2009 recante modifica del regolamento (CE) n. 1907/2006 del Parlamento europeo e del Consiglio concernente la registrazione, la valutazione, l'autorizzazione e la restrizione delle sostanze chimiche (REACH) per quanto riguarda l'allegato XVII

Circolare del ministero della salute 12 aprile 2011

Riferimento certificato di conformità CE n°: 26556

Emesso dall'Ente Notificato n°: 0546 CERTIQUALITY SRL- Via Gaetano Giordano, 4- 20123 MILANO- ITALY

Prima emissione: 20/02/2004

Emissione corrente: 22/03/2021

Luogo: Gordona

Il legale rappresentante
(responsabile rilascio del prodotto)

Data emissione documento_24/01/2024_

DISPOTECH S.R.L.
Via Al Piano, 29
23020 GORDONA (SO)
Tel. 0039 0343 36711 Fax 0039 0343 36567
Codice Fiscale e Partita Iva 00672170149

Dispotech srl Via al piano, 29 23020 GORDONA (SO) Italia

Tel. +39 0343 36711 - Fax. +39 0343 36567 - e-mail: info@dispotech.it - www.dispotech.com

Cap Soc. € 1.500.000,00 i.v. - P. IVA 00672170149 - SDI BA6ET11 - R.E.A. 47213 C.C.I.A.A. di SO - Uff. Reg. Imp. SO 00672170149



Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|--|
| Manufacturer name | Dispotech srl |
| Manufacturer address and contact details | Via al piano, 29 23020 GORDONA (SO) Italia Tel. +39 0343 36711 Fax. +39 0343 36567 e-mail: info@dispotech.it |
| Single Registration Number (SRN) (if available) | IT-MF-000010735 |

| | |
|---|------|
| Authorised Representative name (if applicable) | N.A. |
| Authorised Representative address and contact details | N.A. |
| Single Registration Number (SRN) (if available) | N.A. |

| | |
|--------------------------------------|--|
| Notified body name (if applicable) | Certiquality srl <input type="checkbox"/> See attached schedule |
| Notified body number (if applicable) | 0546 |

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.



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| | |
|---|--|
| | <input type="checkbox"/> See attached schedule |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | 26556 <input type="checkbox"/> See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 28/01/2024 <input type="checkbox"/> See attached schedule |
| End date of extended validity/transition period | 31/12/2028 <input type="checkbox"/> See attached schedule |

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- Expired *before* 20 March 2023:
 - Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
 - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



YOUR DISPOSABLE EXCELLENCE



- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.



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Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Page 4 of 6

Dispotech srl Via al piano, 29 23020 GORDONA (SO) Italia

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Full Company Name DISPOTECH SRL

Location & Date GORDONA, 27/09/2023

Signature, Print Name, Title Mr MASSIMO MORTAROTTI, LEGAL REPRESENTATIVE

DISPOTECH S.R.L.
Via Al Piano, 29
23020 GORDONA (SO)
Tel. 0349 0343 36711 Fax 0349 36567
Codice Fiscale e Partita Iva 00672170149



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number) | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|--|---|--|--|---|---|---|
| INSTANT COLD PACK | 26556 | 28/01/2024 | 0546 | 1936 | 31/12/2028 | n.a. |
| ICE SPRAY | 26556 | 28/01/2024 | 0546 | 1936 | 31/12/2028 | n.a. |
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| | | | | | | |

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)