**Organismo Notificato 0373**
*Notified Body 0373*

# Istituto Superiore di Sanità

Certificato n° *Certificate no.* **EPG-0302-20**

Addendum n° *addendum no.* //-//

Data prima emissione *First issue date* **26.06.2020**
Data di emissione corrente *Current issue date* **26.06.2020**
Data di scadenza *Expiry date* **26.05.2024**

## ESAME CE DELLA PROGETTAZIONE DEL PRODOTTO

## *EC DESIGN-EXAMINATION CERTIFICATE*

secondo l'Allegato II (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
*(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)*

according to Annex II (4) of EC Directive 93/42/EEC and subsequent modifications and integrations
*(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)*

**L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il fascicolo di progettazione del dispositivo medico**

*The Istituto Superiore di Sanità, Notified Body 0373, certifies that the design dossier relating to the medical device*

*(vedi allegato tecnico/ see technical sheet)**

**fabbricato da** *manufactured by*

***TIASET di Carresi Lorenzo***

***Sede Legale/** Registered Office:*
***Loc. Valimeli, 5 – Faella - 52026 Castelfranco Piandiscò (AR) ITALIA***

*Altre sedi del Fabbricante /Other sites of the Manufacturer:*
***Sede Produttiva/** Production Site: **Via Botriolo, 71 – 52026 Castelfranco Piandiscò (AR) Italia***

**è stato sottoposto a verifica, conformemente ai requisiti dell'Allegato II (4), della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.**

*has been submitted to verification, according to Annex II (4), of Council Directive 93/42/EEC and subsequent modifications and integrations.*

**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

*** L'allegato tecnico è parte integrante del presente Certificato**
*The technical sheet is an integral part of this Certificate.*

Organismo Notificato 0373
*Notified Body 0373*

# *Istituto Superiore di Sanità*

## ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **EPG-0302-20**

Addendum n° / *addendum no.* //-//

*di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:*

*of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:*

| ***Classe III*** *(Class III)* |
|---|

| ***Nome prodotto*** *(Product name)* |
|---|
| *Dermadine Plus, sterile* |

Valutazione della Conformità: MOD-341-01-01 n° 247/20
*Conformity assessment: MOD-341-01-01 n. 247/20*

**Il Direttore dell'Organismo Notificato**
*The Director of Notified Body*
**(Dott.ssa Roberta Marcoaldi)**

Roberta Marcoaldi

# 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 | TIASET DI CARRESI LORENZO |
| Manufacturer address and contact details | VIA DELLE CANTINE 30, SAN CIPRIANO 52022 (AREZZO) ITALY |
| Single Registration Number (SRN) (if available) | IT-MF-000027518 |

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

| | |
|---|---|
| Notified body name (if applicable) | SUPERIOR HEALTH INSTITUTE |
| Notified body number (if applicable) | 0373 |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | QCT015620 |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 26/5/2024 |
| End date of extended validity/transition period | 31/12/2027 |

We, as the manufacturer declare under our sole responsibility:

[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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R.E.A nr: AR-154836 A.I.A nr: 54010
Coordinate bancarie: IBAN IT 26 M 08811 71600 000000029249 Banca del Valdarno Ag. sede

- 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
  ☐ 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.

[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



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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.



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**Signed for and on behalf of the manufacturer:**

Full Company Name TIASET DI CARRESI LORENZO

Location & Date SAN CIPRIANO CAVRIGLIA (AREZZO) 52022, 18March 2024

Signature, Print Name, Title CARRESI CLIZIA QUALITY CONTROL

Contact Details (at least email) TIASET.CARRESI@GMAIL.COM

TIASET di CARRESI LORENZO
Cod. Fisc. CRR LNZ 84B20 F656W
Part. IVA 01999370511





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**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) |
|---|---|---|---|---|---|---|
| **DERMADINE PLUS**<br><br>**All**<br>**REF 4XXXXP** | QCT015620 | QCT015620 | **0373** | **0373** | **31/12/2027** | **-** |
| | | | | | | |
| | | | | | | |
| | | | | | | |

[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)



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