

**DICHIARAZIONE DI CONFORMITA'  
ALLA DIRETTIVA 93/42/CEE  
SUI DISPOSITIVI MEDICI**

Il Fabbricante

**FISIOPRESS SRL**

Via Giacomo Boni n° 20  
63822 Porto San Giorgio FM  
ITALIA

DICHIARA SOTTO LA PROPRIA RESPONSABILITA' CHE IL PRODOTTO

**PRESSOTERAPIA SEQUENZIALE  
MODELLO:  
FP 50/FP 4 SSP DIGITAL  
FP 4 SSP DIGITAL/FP 250 DIGITAL  
FP 1000 DIGITAL**

È conforme ai requisiti essenziali di sicurezza dall'allegato I ed alle prescrizioni come previsto da allegato II escluso il punto 4 della direttiva comunitaria 93/42/CEE, recepita in Italia con D.L. n° 46 del 24 febbraio 1997 e successive modifiche compresa la 2007/47/CEE recepita in Italia con DL 25 gennaio 2010, n. 37, come risulta dal certificato MED n° 9839 rilasciato dall'Organismo Notificato KIWA CERMET ITALIA Via Cadriano,

23, 40057 Cadriano di Granarolo (BO) n° 0476.

Classe di rischio IIa

Porto San Giorgio 18/03/2026

**FISIOPRESS SRL**  
Via Giacomo Boni 20  
63822 Porto San Giorgio (FM)  
P. Iva: 01590520449



(L'AMMINISTRATORE UNICO)



Milano, 19 Luglio 2023  
C/0416/23/GL/mab

Spett.le Fisiopress Srl  
Via Giacomo Boni 20  
63822 - Porto San Giorgio (FM)

Bureau Veritas Italia SpA

**OGGETTO: Lettera di Conferma** in riferimento al Certificato di Marcatura CE n° **MED 9839 rev. 6 – DIRETTIVA 93/42/CEE e s.m.i.**

Con la presenta lettera, Bureau Veritas Italia SpA, organismo notificato in accordo al regolamento (EU) 2017/745 (MDR) e identificato dal numero 1370 su NANDO, conferma di aver siglato un accordo scritto numero 4363778, in accordo con la sezione 4.3 secondo sottoparagrafo dell'allegato VII al regolamento (EU) 2017/745 (MDR), con il seguente fabbricante per i dispositivi riportati in tabella n. 1.

Fisiopress Srl  
Via Giacomo Boni 20  
63822 – Porto San Giorgio (FM)

Tabella n.1

| <b>Nome del dispositivo medico o UDI-DI di base riportato nel contratto MDR</b>   | <b>Classe di rischio del dispositivo secondo MDR (come proposto dal fabbricante e verificato in fase di pre-application)</b> | <b>Nome del dispositivo sotto MDD corrispondente al dispositivo per cui è stato firmato il contratto per MDR</b>  | <b>Numero certificato MDD/ AIMDD del dispositivo per cui è stato firmato il contratto per MDR</b> |
|---|--|---|---|
| Apparecchiature per pressoterapia sequenziale (FP1000 DIGITAL, FP250 DIGITAL, FP4, FP4 Fxx, FP4 MEDIPRESS, FP4 MEDIPRESS 8 SETTORI, FP4 MINI, FP4 PENNY, FP4 PROFLOW, FP4 SSP, FP4 SSP DIGITAL, FP4 VARIMEDPRESS, FP4 VENOSANPRESS, FP4/8, FP50, MEDIPRESS EASY, SEQUENTIAL 4 MINI, SEQUENTIAL 6 SETTORI) | Ila  | Apparecchiature per pressoterapia sequenziale (FP1000 DIGITAL, FP250 DIGITAL, FP4, FP4 Fxx, FP4 MEDIPRESS, FP4 MEDIPRESS 8 SETTORI, FP4 MINI, FP4 PENNY, FP4 PROFLOW, FP4 SSP, FP4 SSP DIGITAL, FP4 VARIMEDPRESS, FP4 VENOSANPRESS, FP4/8, FP50, MEDIPRESS EASY, SEQUENTIAL 4 MINI, SEQUENTIAL 6 SETTORI) | Certificato n. MED 9839 rev. 6 emesso il 22/09/2018   |



In accordo al regolamento (UE) 2023/607 del Parlamento Europeo del Consiglio del 15 marzo 2023, Bureau Veritas Italia con la presente lettera conferma che:

- a. L'accordo sopra menzionato (n. 4363778) è stato firmato prima della data di scadenza (22/09/2023) del certificato riportato in Tabella n.1.
- b. Bureau Veritas Italia Spa sarà responsabile, esclusivamente a partire dal 26/09/2024, dell'appropriata sorveglianza dei dispositivi medici certificati sotto Direttiva 93/42/CEE e s.m.i. corrispondenti ai dispositivi medici per cui è stato siglato un accordo per la certificazione secondo il regolamento (EU) 2017/745 (MDR) come riportato in Tabella n.1.

Come previsto dal Regolamento (UE) 2023/607 la validità del certificato MDD n. 9839 rev.6 è estesa fino alla data 31/12/2028 assunto che il fabbricante continui a rispettare tutte le condizioni applicabili specificate dal Regolamento (UE) 2023/607.

### Tabella delle revisioni

| Data       | Revisione |                 |
|------------|-----------|-----------------|
| 19/07/2023 | 0         | Prima emissione |

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

# FISIOPRESS SRL

Sede Legale:  
Via Giacomo Boni 20  
63822 Porto San Giorgio FM  
Sede Commerciale e Service:  
Via Mori 6  
40054 Prunaro di Budrio BO

## 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*<sup>1</sup>
- 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                               |                   |
| Manufacturer address and contact details        | FISIOPRESS s.r.l. |
| Single Registration Number (SRN) (if available) | IT-MF-000026366   |

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

|  |                                      |
|--|--------------------------------------|
| Notified body name (if applicable)   | KIWA Cermet Italia s.p.a             |
| Notified body number (if applicable)   | 0476 <input type="checkbox"/>        |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | 9839 rev. 6 <input type="checkbox"/> |

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<sup>1</sup> 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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|   |            |
|---|------------|
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 22/09/2023 |
| End date of extended validity/transition period   | 31/12/2028 |

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*<sup>2</sup>
- 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

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<sup>2</sup> 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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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.

- 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.

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- 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:

Full Company Name

FISIOPRESS srl

Location & Date 11/09/2023., Prunaro di Budrio (BO)



Signature, Print Name, Title

Ing Alessandro Offidani

Contact Details (at least email) [info@fisiopress.com](mailto:info@fisiopress.com)

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## Schedule of Devices

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

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name, device model or catalogue number)  | Directive Certificate number(s) to which this confirmation is made<br>(if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity<br>(if applicable) | Notified Body name and number that issued the Directive Certificate<br>(if applicable) | Notified Body name and number where the MDR application was lodged/contract signed<br>(if applicable) | End date of extended validity / transition period | Substitute Device(s)<br>(if applicable)   |
|---|---|--|--|---|---|---|
| Apparecchiature per pressoterapia sequenziale (FP1000 DIGITAL, FP250 DIGITAL, FP4, FP4 Fxx, FP4 MEDIPRESS, FP4 MEDIPRESS 8 SETTORI, FP4 MINI, FP4 PENNY, FP4 PROFLOW, FP4 SSP, FP4 SSP DIGITAL, FP4 VARIMEDPRESS, FP4 VENOSANPRESS, FP4/8, FP50, MEDIPRESS EASY, SEQUENTIAL 4 MINI, SEQUENTIAL 6 SETTORI) | <u>MED 9839 rev. 6</u>  | <u>22/09/2023</u><br>(if applicable)   | <u>KIWA 0476</u><br>(if applicable)  | <u>Bureau Veritas Italia SpA 1370</u><br>(if applicable)  | <u>31/12/2028</u>                                 | Apparecchiature per pressoterapia sequenziale (FP1000 DIGITAL, FP250 DIGITAL, FP4, FP4 Fxx, FP4 MEDIPRESS, FP4 MEDIPRESS 8 SETTORI, FP4 MINI, FP4 PENNY, FP4 PROFLOW, FP4 SSP, FP4 SSP DIGITAL, FP4 VARIMEDPRESS, FP4 VENOSANPRESS, FP4/8, FP50, MEDIPRESS EASY, SEQUENTIAL 4 MINI, SEQUENTIAL 6 SETTORI) |

<sup>3</sup> 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)