CERTIFICATO CE

Certificato n. 928/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

SILFRADENT SRL

47018 SANTA SOFIA (FC) - VIA GIUSEPPE DI VITTORIO 35/37 (ITA) - Italy

mantiene nello stabilimento di:

47018 SANTA SOFIA (FC) - VIA GIUSEPPE DI VITTORIO 35/37 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Dispositivi per chirurgia ossea ad ultrasuoni

Micromotori per implantologia

Centrifuga per la produzione di coaguli di fibrina

Inserti per dispositivi per chirurgia ossea ad ultrasuoni

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

10AG00029; 10AH00111; 10AI00149; 10AJ00082; 10AI00093; 10AJ00249; 10AJ00148; 10AK00173; 10AL00053; COMEDCONMHDM110038214-01; COMEDCONMHDM120106745-01; DM13A0170606-01; DM15A0405086-01; DM15E0536846-01; DM16A0638116-01; DM17-0015510-01; DM19-0044477-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2006-07-11
Data aggiornamento:	2020-01-08
Sostituisce:	2019-02-05
Data scadenza:	2024-05-26

IMQ

CERTIFICATO CE

Certificato n. 928/MDD

Allegato

Dispositivi per chirurgia ossea ad ultrasuoni
Modd. SURGYBONE; SURGYBONE SB 400; SURGYBONE SB 400L.
Marca SILFRADENT

Micromotori per implantologia
Mod. EASYBONE Quattro.
Marca SILFRADENT

Centrifuga per la produzione di coaguli di fibrina
Mod. MEDIFUGE CGF.
Marca SILFRADENT

Mod. ROUND UP.
Marca SILFRADENT

Mod. MEDIFUGE MF 100 (versioni MF 100 e MF 100 100).
Marca SILFRADENT

Inserti per dispositivi per chirurgia ossea ad ultrasuoni
Modd. SB P0100; SB P0301; SB P0500; SB P0600; SB P0610; SB P0700; SB P0710; SB P0720; SB P0750; SB P0830; SB P0900; SB P0940; SB P0310; SB P0321; SB P0400; SB P0200; SB P0800; SB P0805; SB P0810; SB P0910; SB P4010; SB P4020; SB P4030; SB P3001; SB P3002; SB P3003; SB P3004; SB P3005; SB P3006; SB P3007; SB P6010; SB P6020; SB P6030; SB P6040; SB P2100; SB P2200; SB P2300; SB P2400; SB P0920; SB P0930; SB P1100; SB P1110; SB P1120; SB P1130; SB P1140.
Marca SILFRADENT

Emesso il:	2006-07-11
Data aggiornamento:	2020-01-08
Sostituisce:	2019-02-05
Data scadenza:	2024-05-26

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IMQ

EC CERTIFICATE

Certificate No 928/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

SILFRADENT SRL

47018 SANTA SOFIA (FC) - VIA GIUSEPPE DI VITTORIO 35/37 (ITA) - Italy

manages in the factory of:

47018 SANTA SOFIA (FC) - VIA GIUSEPPE DI VITTORIO 35/37 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Equipment for bone ultrasound surgery

Micromotors for implantology

Centrifuge for fibrin clots production

Inserts for equipment for bone ultrasound surgery

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AG00029; 10AH00111; 10AI00149; 10AJ00082; 10AI00093; 10AJ00249; 10AJ00148; 10AK00173; 10AL00053; COMEDCONMHDM110038214-01; COMEDCONMHDM120106745-01; DM13A0170606-01; DM15A0405086-01; DM15E0536846-01; DM16A0638116-01; DM17-0015510-01; DM19-0044477-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2006-07-11
Updated:	2020-01-08
Substitution Date:	2019-02-05
Expiry Date:	2024-05-26

DocuSign

IMQ

EC CERTIFICATE

Certificate No 928/MDD

Annex

Equipment for bone ultrasound surgery
Type ref. SURGYBONE; SURGYBONE SB 400; SURGYBONE SB 400L.
Trade mark SILFRADENT

Micromotors for implantology
Type ref. EASYBONE Quattro.
Trade mark SILFRADENT

Centrifuge for fibrin clots production
Type ref. MEDIFUGE CGF.
Trade mark SILFRADENT

Type ref. ROUND UP.
Trade mark SILFRADENT

Type ref. MEDIFUGE MF 100 (version MF 100 and MF 100 100).
Trade mark SILFRADENT

Inserts for equipment for bone ultrasound surgery
Type ref. SB P0100; SB P0301; SB P0500; SB P0600; SB P0610; SB P0700; SB P0710; SB P0720; SB P0750; SB P0830; SB P0900; SB P0940; SB P0310; SB P0321; SB P0400; SB P0200; SB P0800; SB P0805; SB P0810; SB P0910; SB P4010; SB P4020; SB P4030; SB P3001; SB P3002; SB P3003; SB P3004; SB P3005; SB P3006; SB P3007; SB P6010; SB P6020; SB P6030; SB P6040; SB P2100; SB P2200; SB P2300; SB P2400; SB P0920; SB P0930; SB P1100; SB P1110; SB P1120; SB P1130; SB P1140.
Trade mark SILFRADENT

Date:	2006-07-11
Updated:	2020-01-08
Substitution Date:	2019-02-05
Expiry Date:	2024-05-26

DocuSign

IMQ

This is a translation of the Italian text, which prevails in case of doubts

REA MI 1595884
C.F./P.I. 12898410159
Cap. Soc. € 4.000.000

N. di protocollo / *Protocol No.*: **FP-3862/24-nc10**

Data / *Date*: **2024/06/21**

Lettera di conferma dell'Organismo Notificato / *Notified Body Confirmation Letter*
Riferimento / *Reference*: 1001C01572209C_CL

A chi di competenza / *To whom it may concern,*

Conferma dello stato di una domanda formale, di un accordo scritto e di un'appropriata sorveglianza nell'ambito del Regolamento (UE) 2023/607 che modifica i Regolamenti (UE) 2017/745 e 2017/746 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici e dispositivi medico-diagnostici in vitro.

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

La presente lettera conferma che IMQ S.p.A., un Organismo Notificato (nel seguito, "ON") designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero 0051 su NANDO, ha ricevuto una domanda formale in conformità alla sezione 4.3, primo comma dell'Allegato VII del MDR e firmato un accordo scritto in conformità alla sezione 4.3, secondo comma dell'Allegato VII del MDR con il seguente **fabbricante**:

*This letter confirms that IMQ S.p.A., a Notified Body (hereinafter, "NB") designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0051 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 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following **manufacturer**:*

SILFRADENT S.R.L.

VIA G. DI VITTORIO 35-37 CAP 47018 SANTA SOFIA (FC)

SRN: IT-MF-000018668

I dispositivi oggetto della domanda formale e dell'accordo scritto di cui sopra sono identificati nelle Tabelle che seguono; in particolare:

- la Tabella 1 identifica i dispositivi per i quali IMQ S.p.A. ha ricevuto una domanda formale MDR, ha concluso un accordo scritto ed è anche responsabile dell'appropriata sorveglianza dei corrispondenti dispositivi ai sensi della Direttiva 90/385/CEE o della Direttiva 93/42/CEE (nel seguito, "(AI)MDD"),
- la Tabella 2 identifica i dispositivi per i quali IMQ S.p.A. ha ricevuto una domanda formale MDR, ha concluso un accordo scritto ma non ha assunto la responsabilità dell'appropriata sorveglianza dei corrispondenti dispositivi ai sensi della (AI)MDD.

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below; in particular:

- *Table 1 identifies the devices for which IMQ S.p.A. has received a MDR formal application, has concluded a written agreement and is also responsible for appropriate surveillance of the corresponding devices under the* Directive 90/385/EEC or Directive 93/42/EEC (hereinafter, "(AI)MDD"),
- *Table 2 identifies the devices for which IMQ S.p.A. has received a MDR formal application, has concluded a written agreement but has not taken the responsibility for appropriate surveillance of the corresponding devices under the (AI)MDD.*

Nel caso di dispositivi oggetto di certificati rilasciati ai sensi della (AI)MDD (nel seguito, "certificato (AI)MDD") che sono scaduti dopo il 26 maggio 2021 e prima del 20 marzo 2023, senza essere stati ritirati, questa lettera conferma anche che il fabbricante ha firmato l'accordo scritto ai sensi del MDR entro la data di scadenza del pertinente certificato (AI)MDD *oppure* ha fornito l'evidenza che un'Autorità Competente di uno Stato membro ha concesso una deroga o un'esenzione dalla procedura di valutazione della conformità applicabile ai sensi, rispettivamente, dell'articolo 59(1)del MDR o dell'articolo 97(1) del MDR, entro il 20 Marzo 2023 per i dispositivi in questione.

In the case of devices covered by certificates issued under (AI)MDD (hereinafter, "(AI)MDD certificate") that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of expiry of the relevant (AI)MDD certificate or provided evidence that a Competent Authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

Di seguito sono riportati i periodi di transizione che si applicano ai dispositivi oggetto della presente lettera, a condizione che il fabbricante continui a rispettare le altre condizioni specificate nell'articolo 120 (3 quater) del MDR (come modificato dal Regolamento (UE) 2023/607):

a) 31 dicembre 2027, per tutti i dispositivi della classe III, e per i dispositivi impiantabili della classe IIb ad eccezione delle tecnologie ben consolidate (WET - materiali per sutura, graffette, materiali per otturazioni dentarie, apparecchi ortodontici, corone dentali, viti, cunei, placche e protesi, fili, chiodi, clip e connettori),

b) 31 dicembre 2028, per i dispositivi della classe IIb diversi da quelli di cui al punto a) che precede, per i dispositivi della classe IIa e per i dispositivi della classe I immessi sul mercato in condizione sterile (Is) o con funzione di misura (Im),

c) 31 dicembre 2028 per i dispositivi per i quali la procedura di valutazione della conformità a norma della MDD non richiedeva l'intervento di un ON ma per i quali la procedura di valutazione della conformità a norma del MDR richiede l'intervento di un ON, ad esempio, dispositivi della classe I che si qualificano come Strumenti chirurgici riutilizzabili (Ir).

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR (as amended by Regulation (EU) 2023/607), are shown below:

a) 31 December 2027, for all class III devices, and for class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors),

b) 31 December 2028, for class IIb devices other than those covered by point (a) above, for class IIa devices, and for class I devices placed on the market in sterile condition (Is) or having a measuring function (Im),

c) 31 December 2028 for devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a NB but for which the conformity assessment procedure pursuant to MDR requires the involvement of a NB, e.g., class I devices that qualify as re-usable surgical instruments (Ir).

Distinti saluti / Best regards

IMQ S.p.A.
Responsabile Divisione Dispositivi Medici
Medical device Division Manager

B. Venturelli
(B. Venturelli)

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** [1]	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
MF 200; MF 200 100	IIa	MEDIFUGE CGF	Certificato / *Certificate*: 928/MDD ON / *NB*: 0051
MF 100; MF 100 100	IIa	MEDIFUGE MF 100	Certificato / *Certificate*: 928/MDD ON / *NB*: 0051
RU 200; RU 200 100	IIa	ROUND UP	Certificato / *Certificate*: 928/MDD ON / *NB*: 0051
SURGYBONE SB 300; SURGYBONE SB 300JM; SURGYBONE SB 300 110; SURGYBONE SB 300 100 SURGYBONE SB 300BR 220; SURGYBONE SB 300BR 110; SURGYBONE 300 NA;	IIa	SURGYBONE; SURGYBONE SB 400; SURGYBONE SB 400L	Certificato / *Certificate*: 928/MDD ON / *NB*: 0051

[1] Classificazione del dispositivo oggetto della Domanda MDR proposta dal fabbricante ai sensi dell'All. VIII del MDR e verificata in via preliminare dall'ON ai sensi della sezione 4.2 (d) dell'Allegato VII del MDR / *Classification of the device under MDR application, as proposed by the manufacturer according to Annex VIII of the MDR and preliminary verified by the NB according to Section 4.2 (d) of Annex VII of the MDR*

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR *Device (Name or Basic UDI-DI) under MDR application*	**Classificazione del Dispositivo oggetto della Domanda MDR** *Classification of the device under MDR application (1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** *If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device*	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** *Reference to relevant (AI)MDD certificate(s) and the NB identification*
SURGYBONE SB 400; SURGYBONE SB 400 100; SURGYBONE SB 400L; SURGYBONE SB 400L 100; SURGYBONE SB 400L BR; SURGYBONE SB 400L BR 100			
Easybone Quattro DI 400; Easybone Quattro DI 400 100; Easybone Quattro DI 500; Easybone Quattro DI 500 100	IIa	EASYBONE Quattro	Certificato / *Certificate*: 928/MDD ON / *NB*: 0051
SB P0100; SB P0301; SB P0500; SB P0600; SB P0610; SB P0700; SB P0710; SB P0720;	IIa	n/a	Certificato / *Certificate*: 928/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD *Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD*			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** (1)	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
SB P0750; SB P0830; SB P0900; SB P0940; SB P0310; SB P0321; SB P0400; SB P0200; SB P0800; SB P0805; SB P0810; SB P0910; SB P4010; SB P4020; SB P4030; SB P3001; SB P3002; SB P3003; SB P3004; SB P3005;			

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD *Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD*			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** (1)	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
SB P3006; SB P3007; SB P6010; SB P6020; SB P6030; SB P6040; SB P2100; SB P2200; SB P2300; SB P2400; SB P0920; SB P0930; SB P1100; SB P1110; SB P1120; SB P1130; SB P1140			

Tabella 2: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. non è responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD *Table 2: Devices covered by this letter and for which IMQ S.p.A. is not responsible for appropriate surveillance of the corresponding devices under the (AI)MDD*			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** (1)	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
n/a	n/a	n/a	n/a

Tabella 3: Storico delle revisioni della presente lettera di conferma ***Table 3: Revision history of this confirmation letter***		
Data / ***Date***	**N. di protocollo** / Protocol No.	**Azione** / Action
2024/06/21	FP-3862/24-nc10	Prima emissione / *First issue*

silfradent®

MEDICAL DEVICES

EQUIPMENT FOR DENTAL LABORATORIES

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	SILFRADENT SRL
Manufacturer address and contact details	VIA GIUSEPPE DI VITTORIO,35/37, 47018 SANTA SOFIA (FC) - Italy Tel. 0543 970684
Single Registration Number (SRN) (if available)	IT-MF-000018668

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

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

[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.

Silfradent srl – via G. Di Vittorio 35/37
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capitale sociale interamente versato Euro 99.000
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www.silfradent.com - e-mail: info@silfradent.com

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
  ☐ 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.

  ☒ 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.

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[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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capitale sociale interamente versato Euro 99.000
reg. imprese FC 01721580403- REA n.212052
www.silfradent.com - e-mail: info@silfradent.com

☐ 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:

SILFRADENT SRL

VIA GIUSEPPE DI VITTORIO,35/37, 47018 SANTA SOFIA (FC) - Italy

01/12/2023

Signature, Print Name, Title Massimo Lungherini – RSQ Assicurazione Qualità

Contact Details (at least email) m.lungherini@silfradent.com

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)
SURGYBONE	928/MDD	26/05/2024	IMQ S.p.A. 0051		31/12/2028	
SURGYBONE SB 400	928/MDD	26/05/2024	IMQ S.p.A. 0051		31/12/2028	
SURGYBONE SB 400L	928/MDD	26/05/2024	IMQ S.p.A. 0051		31/12/2028	
EASYBONE Quattro	928/MDD	26/05/2024	IMQ S.p.A. 0051		31/12/2028	
MEDIFUGE CGF	928/MDD	26/05/2024	IMQ S.p.A. 0051	IMQ S.p.A. 0051	31/12/2028	
ROUND UP	928/MDD	26/05/2024	IMQ S.p.A. 0051	IMQ S.p.A. 0051	31/12/2028	
MEDIFUGE MF 100	928/MDD	26/05/2024	IMQ S.p.A. 0051	IMQ S.p.A. 0051	31/12/2028	
SB P0100; SB P0301; SB P0500; SB P0600; SB P0610; SB P0700; SB P0710; SB P0720; SB P0750; SB P0830; SB P0900; SB P0940; SB P0310; SB P0321; SB P0400; SB P0200; SB P0800; SB P0805; SB P0810; SB P0910; SB P4010; SB P4020; SB P4030;	928/MDD	26/05/2024	IMQ S.p.A. 0051		31/12/2028	

[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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codice fiscale e P. IVA nr. 01721580403
capitale sociale interamente versato Euro 99.000
reg. imprese FC 01721580403- REA n.212052
www.silfradent.com - e-mail: info@silfradent.com

SB P3001; SB P3002; SB P3003; SB P3004; SB P3005; SB P3006; SB P3007; SB P6010; SB P6020; SB P6030; SB P6040; SB P2100; SB P2200; SB P2300; SB P2400; SB P0920; SB P0930; SB P1100; SB P1110; SB P1120; SB P1130; SB P1140						

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Dichiarazione CE di conformita'

Certificat CE de conformite'

CE declaration of conformity

Declaracion CE conforme

Übereinstimmungsbescheinigung

silfradent®

CSQ MED ISO 13485:2003 | CSQ ISO 9001:2008 | IQNet ISO 9001:2008

ai sensi della DIRETTIVA
aux termes de la DIRECTIVE
in accordance with DIRECTIVES
a la DIRECTIVA
im Sinne der EWG-Richtline

93/42/EEC

e successive modificazioni
et de ses modifications ultérieures
and subsequent modifications
y sucesivas modificaciones
und folgender Änderungen

Il Fabbricante, Le Fabricant, The Manufacturer, El Fabricante, Der Hersteller

silfradent *s.r.l.* via G. Di Vittorio, 35/37 - 47018 S.Sofia (FORLI') - ITALY

dichiara sotto la propria responsabilita'che la macchina/dispositivo:

déeclare sous sa propre responsabilité que la machine/dispositif:

declares, under its own responsability, that the following equipment/device:

déclara bajo su responsabilidad que la maquina/dispositivo:

erklärt unter eigener Verantwortung, daß das Gerät/Medizinprodukt:

Product Categories	CENTRIFUGA PER LA PRODUZIONE DI COAGULI DI FIBRINA
Model :	**MEDIFUGE CGF** — Int. Code **MEDIFUGE CGF**
Description :	**CENTRIFUGA MEDIFUGE completa del Kit CGF K1**

Classification : Class IIa **Rule : 3**

Numero di serie , Numéro de serie , Serial No , Número de serie , Serienummer :

da : **YYYY-XXX-ZZZ** a : **YYYY-XXX-ZZZ**

Anno di costruzione , Year of manufacturing , Année de construction , Baujahr : **2017**

e' conforme ai requisiti essenziali di sicurezza e tutela della salute di cui alle DIRETTIVE
est conforme aux conditions essentielles en matèrie de sécurité et de sauvegarde de la santé, aux termes des Directives
complies with the essential requirements of safety and safeguarding of healt, set down in the DIRECTIVES
es conforme a los requisitos esenciales de seguridad y de proteccion de salud que indica la DIRECTIVA
den wesentlichen Sicherheits- und Gesundheitsschutzforderungen gemäß die EWG-Richtlinie erfuellt

93/42/EEC (in accordo con l'Allegato II), CE 0051

Il Responsabile, Batani Tiziano

S.Sofia li: **20/03/2017**

Dichiarazione CE di conformita'

Certificat CE de conformite'

CE declaration of conformity

Declaracion CE conforme

Übereinstimmungsbescheinigung

silfradent®

CSQ MED ISO 13485: 2016 | CSQ IQNet ISO 9001:2015 | IQNet ISO 9001:2015

ai sensi della DIRETTIVA
aux termes de la DIRECTIVE
in accordance with DIRECTIVES
a la DIRECTIVA
im Sinne der EWG-Richtline

93/42/EEC

e successive modificazioni
et de ses modifications ultérieures
and subsequent modifications
y sucesivas modificaciones
und folgender Änderungen

Il Fabbricante, Le Fabricant, The Manufacturer, El Fabricante, Der Hersteller

silfradent *s.r.l.* via G. Di Vittorio, 35/37 - 47018 S.Sofia (FORLI') - ITALY

dichiara sotto la propria responsabilita'che la macchina/dispositivo:

déeclare sous sa propre responsabilité que la machine/dispositif:

declares, under its own responsability, that the following equipment/device:

déclara bajo su responsabilidad que la maquina/dispositivo:

erklärt unter eigener Verantwortung, daß das Gerät/Medizinprodukt:

Product Categories	CENTRIFUGA PER LA PRODUZIONE DI COAGULI DI FIBRINA
Model :	**MEDIFUGE MF 100** Int. Code **MF 100**
Description :	**CENTRIFUGA MEDIFUGE MF 100 230 Vac**

Classification : Class IIa **Rule : 3**

Numero di serie , Numéro de serie , Serial No , Nùmero de serie , Serienummer :

da : a :

Anno di costruzione , Year of manufacturing , Année de construction , Baujahr : **2020**

e' conforme ai requisiti essenziali di sicurezza e tutela della salute di cui alle DIRETTIVE

est conforme aux conditions essentielles en matèrie de sécurité et de sauvegarde de la santé, aux termes des Directives

complies with the essential requirements of safety and safeguarding of healt, set down in the DIRECTIVES

es conforme a los requisitos esenciales de seguridad y de proteccion de salud que indica la DIRECTIVA

den wesentlichen Sicherheits- und Gesundheitsschutzforderungen gemäß die EWG-Richtlinie erfuellt

93/42/EEC (in accordo con l'Allegato II), CE 0051

come da Certificato n. 928/MDD rilasciato da IMQ S.p.a. organismo notificato n. 0051

Il Responsabile, Batani Tiziano

S.Sofia li:

Batani Tiziano