bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01085**

Issued To: **Sofic**
3 Rue Jean-Jacques Rousseau
B. P. 282 - Aussillon
Mazamet Cedex
81207
France

In respect of:

The design, development and manufacture of sterile and non-Sterile single use devices: medical and dental needles for hypodermic injections; medical and dental safety devices for hypodermic injections.

For those aspects related to securing and maintaining sterility in the manufacture of Sterile Single Use Handle for Protective Injection Device.

For scope translation in French refer to supplementary page

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-12-12** Date: **2020-04-16** Expiry Date: **2024-05-26**

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SOFIC,

3, Rue Jean-Jacques Rosseau,

B.P. 282 - Aussillon,

Mazamet Cedex,

81207

France.

CONFiDENTIAL

14-09-2023

Notified Body Confirmation Letter

Reference: EU2023-607/ 689177

To whom it may concern,

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 (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

SOFIC,

3, Rue Jean-Jacques Rosseau,

B.P. 282 - Aussillon,

Mazamet Cedex,

81207

France.

SRN Number: FR-MF-000004168

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) 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 MDD/AIMDD certificate expiry; 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 the 20 Mar 2023 for the relevant devices.

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 (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Ffion O'Malley

Digitally signed by Ffion O'Malley
Date: 2023.09.14 14:47:35 +01'00'

Ffion O'Malley

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SOFICONCEPT/SOFICONCEPT XL/INIBSAJECT PLUS 35231000002EJ	Class IIa	N/A	EC Certificate Annex II excluding section 4 – Full Quality Assurance certificate CE 01085 exp 2024/05/26 BSI 2797
SOFIJET/BADIJECT/SOFIJET EVOLUTION/XL by SOFIC (and associated private brand names) 35231000001EG	Class IIa	N/A	EC Certificate Annex II excluding section 4 – Full Quality Assurance certificate CE 01085 exp 2024/05/26 BSI 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

~~Device name or Basic UDI-DI (under MDR application)~~	~~MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)~~	~~If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device~~	~~MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification~~
~~Device 1~~	~~Choose an item.~~	~~N/A~~	~~N/A~~

Confirmation Letter Revision History

Date	Action
2023/09/14	Initial issue

SOFIC
3 Rue Jean-Jacques Rousseau
BP 282, Aussillon,
81207 Mazamet Cedex
Tel: +33(0)5 63 97 57 18

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and / or*
- the compliance of the devices with the conditions for the continued placing on the market and putting into service

Manufacturer name	SOFIC
Manufacturer address and contact details	3 Rue Jean-Jacques Rousseau BP 282, Aussillon, 81207 Mazamet Cedex FRANCE

We, as the manufacturer declare under our sole responsibility that:

- the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met for the listed **Directive Certificate(s)** in attached schedule and / or
- being in compliance with the conditions listed in Article 120.3c of the MDR to continue placing on the market and putting into service the listed **device(s)** in the attached schedule

namely by fulfilling the following conditions:

- **Directive Certificate(s)** in the attached schedule
  - Directive Certificate(s) covering the listed device(s) were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
  - Formal applications to notified bodies in accordance with Section 4.3, first subparagraph of MDR Annex VII for conformity assessment will be submitted at the latest on December 2023
  - Signed written agreements will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR at the latest on 26 September 2024
- **Quality Management System (QMS)**
  - A QMS in accordance with Article 10(9) MDR is in place.
- **Device(s) as listed** in the attached schedule
  - The device(s) continue to comply with the 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.

Aussillon, 24th May 2024

Cédric LEBASTARD
Person Responsible for Regulatory Compliance

Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number for MDR Certification	End of the transition period
SOFIJET **BADIJECT** **XL by SOFIC** **SOFIJET Evolution**	CE 01085 (date: 2020-04-16) (Approval of full Quality Assurance System-Annex II excluding section 4)	May 26th, 2024	BSI:2797	BSI:2797	31 December 2028
SOFICONCEPT **SOFICONCEPT XL**	CE 01085 (date: 2020-04-16) (Approval of full Quality Assurance System-Annex II excluding section 4)	May 26th, 2024	BSI:2797	BSI:2797	31 December 2028

Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number for MDR Certification	End of the transition period
SOPIRA® Carpule® Dental Needles **SeleKt+ Dental Needles** **SOPIRA® Carpule® Dental Needles Free Flow**	CE 01085 (date: 2020-04-16) (Approval of full Quality Assurance System-Annex II excluding section 4)	May 26th, 2024	BSI:2797	BSI:2797	31 December 2028