EC Certificate - Full Quality Assurance System

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

No. **CE 699273**

Issued To: **Braile Biomédica Indústria, Comércio e Representações Ltda.**
Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf
São José do Rio Preto
São Paulo
15091-450
Brasil

In respect of:

Design, development and manufacture of sterile Cardiopulmonary Bypass Kits and Components including Membrane Oxygenators, Tubes and Blood Reservoirs.

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: **2020-10-20** Date: **2020-10-20** Expiry Date: **2024-05-26**

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Supplementary Information to CE 699273

Issued To:

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Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf
São José do Rio Preto
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15091-450
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD0102	Cardiopulmonary Bypass kits and components	---

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 699273**
Date:	**2020-10-20**
Issued To:	**Braile Biomédica Indústria, Comércio e Representações Ltda.** **Av. Pres. Juscelino Kubitschek de Oliveira, 1505** **Jardim Tarraf** **São José do Rio Preto** **São Paulo** **15091-450** **Brasil**

Subcontractor:	**Service(s) supplied**
Mars Medical Landhausstraße 46 Stuttgart 70190 Germany	**EU Representative**
Oximed - Tecnologia em Esterilização Eireli Rua Ulysses Jamil Cury, 920 Distrito Industrial São José do Rio Preto São Paulo 15092-601 Brazil	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 699273**

Date: **2020-10-20**

Issued To: **Braile Biomédica Indústria, Comércio e Representações Ltda.**
Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf
São José do Rio Preto
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Certificate History

Date	Reference number	Action
20 October 2020	9645320	First Issue
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
23 December 2021	3563207	The authorized representative changed from Obelis S.A to Mars Medical.

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23 December 2021

Braile Biomédica Indústria, Comércio e
Representações Ltda.
Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf
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15091-450
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 699273	93/42/EEC Annex II excluding Section 4	3563207	The authorized representative changed from: Obelis S.A Bd. Gènèral Wahis, 53 1030 Brussels Belgium to: Mars Medical Landhausstraße 46 70190 Stuttgart Germany

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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Braile Biomédica Indústria, Comércio e Representações Ltda.
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Jardim Tarraf I
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15091-450
Brasil

20 May 2024

Notified Body Confirmation Letter

Reference: EU2023-607/868744

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:

Braile Biomédica Indústria, Comércio e Representações Ltda.
Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf I
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São Paulo
15091-450
Brasil
SRN Number: BR-MF-000016583

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.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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
789871635622276-6Z	Class IIa	N/A	CE 699273; NB #2797
789871635622278-75	Class IIa	N/A	CE 699273; NB #2797
789871635622280-6Q	Class IIa	N/A	CE 699273; NB #2797
789871635622282-6U	Class IIa	N/A	CE 699273; NB #2797
789871635622284-6Y	Class IIa	N/A	CE 699273; NB #2797
789871635622375-74	Class IIa	N/A	CE 699273; NB #2797
789871635622378-7A	Class IIa	N/A	CE 699273; NB #2797
789871635622257-6V	Class IIa	N/A	CE 699273; NB #2797
789871635622261-6L	Class IIa	N/A	CE 699273; NB #2797
789871635622266-6W	Class IIa	N/A	CE 699273; NB #2797
789871635622271-6P	Class IIa	N/A	CE 699273; NB #2797
789871635622381-6X	Class IIa	N/A	CE 699273; NB #2797
789871635622383-73	Class IIa	N/A	CE 699273; NB #2797
78987163510159030111-GD	Class IIa	N/A	CE 699273; NB #2797
789871635622286-74	Class IIa	N/A	CE 699273; NB #2797
789871635622290-6T	Class IIa	N/A	CE 699273; NB #2797
789871635622294-73	Class IIa	N/A	CE 699273; NB #2797
789871635622298-7B	Class IIa	N/A	CE 699273; NB #2797
789871635622302-69	Class IIa	N/A	CE 699273; NB #2797
78987163510159039001-J4	Class IIa	N/A	CE 699273; NB #2797
789871635622258-6X	Class IIa	N/A	CE 699273; NB #2797
789871635622262-6N	Class IIa	N/A	CE 699273; NB #2797
789871635622267-6Y	Class IIa	N/A	CE 699273; NB #2797
789871635622272-6R	Class IIa	N/A	CE 699273; NB #2797
789871635622277-73	Class IIa	N/A	CE 699273; NB #2797
789871635622279-77	Class IIa	N/A	CE 699273; NB #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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/05/20	Initial issue