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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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 699273

Issued To:

Braile Biomédica Indústria, Comércio e Representações Ltda.
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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**

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Av. Pres. Juscelino Kubitschek de Oliveira, 1505
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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
São José do Rio Preto
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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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