

EC Certificate - Full Quality Assurance System

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

No.**CE 685475****Issued To:**

**Atrasorb Industria
de Produtos Hospitalares Ltda
Av. Piracicaba, 351
Vila Nova São Roque
São Roque
São Paulo
18131-230
Brasil**

In respect of:

Design and manufacture of carbon dioxide absorbers for anaesthesia devices.

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: **2019-07-31**

Date: **2019-07-31**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 685475

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0101	Atrasorb Pharma	---
MD 0101	Atrasorb Pharma Free	---
MD 0101	Astrasorb Pharma FIX	---

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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 de Produtos Hospitalares Ltda
 Av. Piracicaba, 351
 Vila Nova São Roque
 São Roque
 São Paulo
 18131-230
 Brasil**

Subcontractor:

Service(s) supplied

CINTERQUAL – Soluções de Comércio Internacional
 Ltda.
 Rua Fran Pacheco
 Nr. 220, 2nd floor
 Setúbal
 2900-374
 Portugal

EU Representative

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Certificate History

Certificate No: **CE 685475**
Date: **2019-07-31**
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Date	Reference Number	Action
Current	8866857	First Issue.

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