

EC Certificate - Full Quality Assurance System

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

No. CE 685022
Issued To: Goodman Co., Ltd.
5F KDX Nagoya Sakae Building,
4-5-3 Sakae,
Naka-ku, Nagoya,
Aichi
460-0008
Japan

In respect of:

Design, development and manufacture of sterile PTA Balloon Dilatation Catheters

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):



Albert Roossien, Regulatory Lead

First Issued: **2018-05-01**

Date: **2019-02-14**

Expiry Date: **2023-04-30**

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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 685022

Issued To:

**Goodman Co., Ltd.
5F KDX Nagoya Sakae Building,
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Aichi
460-0008
Japan**

Devices

Class IIa
NSE PTA Balloon Dilatation Catheter

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

List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Goodman Co., Ltd. Medical Innovation Center 277-1 Idogane-cho, Seto, Aichi 489-0976 Japan	Design
Goodman Co., Ltd. Goodman Research Center 276-1 Idogane-cho, Seto, Aichi 489-0976 Japan	ETO Sterilization Manufacture Packaging
Goodman Medical Ireland Ltd Mervue Business Park Galway Ireland	EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Certificate History

Date	Reference Number	Action
01 May 2018	8863923	First issue.
Current	8863927	Traceable to NB 0086.

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