By Royal Charter

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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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 685022

Issued To:

Goodman Co., Ltd.
5F KDX Nagoya Sakae Building,
4-5-3 Sakae,
Naka-ku, Nagoya,
Aichi
460-0008
Japan

Devices

Class IIa
NSE PTA Balloon Dilatation Catheter

First Issued: **2018-05-01** Date: **2019-02-14** Expiry Date: **2023-04-30**

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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:

Certificate No:	**CE 685022**
Date:	**2019-02-14**
Issued To:	**Goodman Co., Ltd.** **5F KDX Nagoya Sakae Building,** **4-5-3 Sakae,** **Naka-ku, Nagoya,** **Aichi** **460-0008** **Japan**

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

Certificate No: **CE 685022**

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Certificate History

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