EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 607483**

Issued To: **Benmor Medical (UK) Limited**
The Aurum Centre
Ham Barn Business Park
Farnham Road
Liss
Hampshire
GU33 6LB
United Kingdom

In respect of:

Those aspects of metrology concerned with the manufacture of patient weighing equipment.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2014-02-25** Date: **2019-02-25** Expiry Date: **2024-02-24**

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Supplementary Information to CE 607483

Issued To:

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Number	Device Name	Intended purpose per IFU
Class Im		
MD 1109	Aurum bed series (with scale)	N/A for class Im devices

First Issued: **2014-02-25** Date: **2019-02-25** Expiry Date: **2024-02-24**

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By Royal Charter

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 607483**
Date:	**2019-02-25**
Issued To:	**Benmor Medical (UK) Limited** **The Aurum Centre** **Ham Barn Business Park** **Farnham Road** **Liss** **Hampshire** **GU33 6LB** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Medical Device Management Ltd Block B, The Crescent Building Northwood Santry Dublin 9 D09 C6X8 Ireland	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 607483**

Date: **2019-02-25**

Issued To: **Benmor Medical (UK) Limited**
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Date	Reference Number	Action
25 February 2014	8075560	First issue.
14 February 2019	9699945	Renewal.
25 February 2019	8895825	Traceable to NB 0086.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
04 March 2022	3599505	Addition of EU Authorised Representative

Inspiring trust for a more resilient world.

04 March 2022

Benmor Medical (UK) Limited
The Aurum Centre
Ham Barn Business Park
Farnham Road
Liss
Hampshire
GU33 6LB
United Kingdom

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 607483	93/42/EEC Annex V	3599505	Addition of EU Authorised Representative: Medical Device Management Ltd, Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland

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,

Graeme Tunbridge
Senior Vice President, Medical Devices

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