

# 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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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.

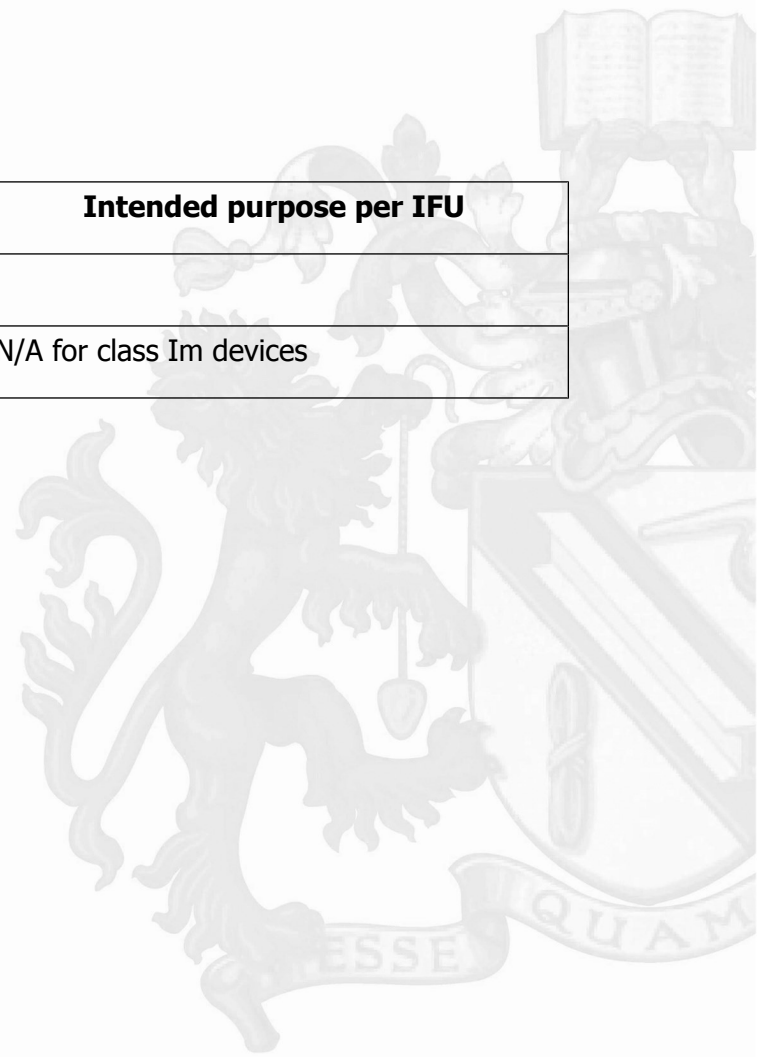
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## Supplementary Information to CE 607483

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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



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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 V

## List of Significant Subcontractors

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

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**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**  
**The Aurum Centre**  
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**Farnham Road**  
**Liss**  
**Hampshire**  
**GU33 6LB**  
**United Kingdom**

Date	Reference Number	Action
25 February 2014	8075560	First issue.
14 February 2019	9699945	Renewal.
25 February 2019	8895825	Traceable to NB 0086.
<b>Non-significant changes approved after the 26<sup>th</sup> May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
04 March 2022	3599505	Addition of EU Authorised Representative

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

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,

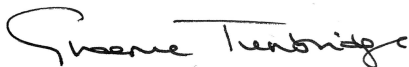
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

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