

EC Certificate - Full Quality Assurance System

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

No.

CE 650520

Issued To:

**Repro-Med Systems, Inc.
also trading as KORU Medical Systems
24 Carpenter Road
Chester
New York
10918
USA**

In respect of:

Design and Manufacture of Infusion Systems, including Infusion Pump, Sterile Flow Rate Controller, Sterile Infusion Tubing Set, Sterile Needle Set and Sterile Suction 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):



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2016-07-05**

Date: **2020-08-24**

Expiry Date: **2024-02-22**

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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 650520

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1101	Infusion Pump	N/A for class IIa devices
MD 0102	Sterile Flow Rate Controller	N/A for class IIa devices
MD 0102	Sterile Infusion Tubing Set	N/A for class IIa devices
MD 0102	Sterile Needle Set	N/A for class IIa devices
MD 0102	Sterile Suction Catheters	N/A for class IIa 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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 650520**
 Date: **2020-08-24**
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Date	Reference Number	Action
05 July 2016	8488712	First issue. Transferred from another notified body.
27 September 2016	8607443	Change of EU Representative address.
27 September 2017	8813811	Change of EU Representative address.
13 February 2019	9716038	Significant subcontractor name change from Steris Isomedix Services to Isomedix Operations, Inc.; addition of Synergy Health Ast, LLC as significant subcontractor for sterilization; certificate renewal.
27 February 2019	9721186	Traceable to NB 0086.

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Date	Reference Number	Action
24 August 2020	3221562	<p>Change of manufacturer's trade name from Repro-Med Systems, Inc. also trading as RMS Medical Products to Repro-Med Systems, Inc. also trading as KORU Medical Systems.</p> <p>Change of EU Representative from RMS Medical Products UK, LTD 123a Allerton Rd Mossley Hill Liverpool L182DD United Kingdom to MedPass International, 95 bis Boulevard Pereire, 75017, Paris, France.</p> <p>Removal of subcontractor Command Medical Products 15 Signal Avenue Ormond Beach FL 32174 USA.</p> <p>Addition of subcontractor Command Medical Nicaragua SA Km 12.5 Carretera Norte, Parque Industrial Las Mercedes Edificio 16, Managua, Nicaragua.</p> <p>Addition of subcontractor Isomedix Operations Inc. 2 Nucifora Boulevard, Chester, New York 10918.</p> <p>Removal of NBOG code MDS 7006 from product table.</p>

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
03 February 2023	3848682	Change of legal manufacturer address and name. Change of EU representative to Icon (LR) Limited.

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03 February 2023

KORU Medical Systems, Inc.
 100 Corporate Drive
 Mahwah
 New Jersey
 07430
 USA

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 650520	93/42/EEC Annex II excluding Section 4	3848682	<p>Change in legal manufacturer address from "24 Carpenter Road, Chester, New York, 10918, USA" to "100 Corporate Drive, Mahwah, New Jersey, 07430, USA" and name change from "Repro-Med Systems, Inc. also trading as KORU Medical Systems" to "KORU Medical Systems, Inc."</p> <p>EU representative changed from: MedPass International 95 Bis Boulevard Pereire 75017, Paris France To: Icon (LR) Limited Leopardstown Dublin 18 D18 X5R3 Ireland</p>

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