EC Certificate - Production Quality Assurance

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

No. **CE 551349**

Issued To: **Bard Access Systems, Inc.**
605 North 5600 West
Salt Lake City
Utah
84116
USA

In respect of:

See certificate scope page.

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: **2009-08-16** Date: **2020-11-11** Expiry Date: **2024-05-26**

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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.

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.
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By Royal Charter

Certificate No: CE 551349

Certificate Scope:

The manufacture of ultrasound scanner systems with probes, catheter repair kits, extension sets and injection caps.
Those aspects of Annex V related to securing and maintaining the sterility in the manufacture of gauzes, sponge sticks, drapes, scissors, clamps, suture wings, flushing hubs, threader stylets, syringes, surgeon gowns, needle holders, absorbent towels, forceps, measuring tapes, transparent dressings, drainage bags, tourniquets, surgeon caps, gloves, masks, remote control covers, catheter tracking device accessories, ultrasound system accessories, skin prep pads and catheter stabilization devices.
Those aspects of Annex V related to metrology and securing and maintaining sterility in the manufacture of stoma measuring devices.

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Supplementary Information to CE 551349

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Surgical Accessories (extension sets and injection caps)	---
MD 0102	Catheter Repair Kits	---
MD 1202	Site-Rite Prevue Ultrasound System	---
MD 1202	Site~Rite 8 Ultrasound System	---
MD 1202	Site~Rite 8 Ultrasound System with Cue Needle Technology	---
Class Is		
MD 0106	Port and Catheter Placement Accessories	---
MD 0106	Catheter Accessories	---
MD 0106	General Surgical Accessories	---
MD 0102	Feeding Accessories	---
MD 0106	Navarre Drainage Products	---
MD 0106	Catheter Tracking Accessories Including ECG Lead (Fin) Assembly, Sensor Holder, 12" Remote Control Cover, ECG Electrodes, and Elastic Bands	---
MD 0106	Nautilus Adaptors (ECG lead wires)	---
MD 0106	Stabilization Device	---
MD 0106	Ultrasound System Accessory	---
Class Is/Im		
MD 0104	Stoma Measuring Device	---

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Date	Reference Number	Action
16 August 2009	7387868	First issue - Transfer from another Notified Body.
04 February 2010	7482205	Combine CE 551353 and CE 551354 with CE 551349, remove Sterigenics, 5725 West Harold Gatty Drive from the list of subcontractors, correct typos on subcontractor listing and renew certificate.
27 May 2010	7533717	Addition of drainage bags to the scope. C.R. Bard, Inc. Queensbury added to the list of significant subcontractors. Added packaging to the list of activities for Bard Shannon.
28 October 2011	7751024	Addition of Tourniquets, surgeon caps, gloves, masks and catheter tracking device accessories.
26 January 2015	8239879	Certificate renewal. Removed the subcontractor "Bard Healthcare-Reynosa" in Texas and "C.R. Bard" division in Madison and Queensbury. Corrected the address of subcontractor Bard Reynosa S.A. de C.V. Add new subcontractor Jiangyin PureMED.
07 July 2016	8523502	Addition of Romedex International SRL to the list of significant subcontractors for manufacturing. Addition of Bard Medical Division and SC Biosintex SRL for ETO sterilization.

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25 July 2017	8696938	Addition of CEA Republica Dominicana to the list of significant subcontractors with the services of manufacture, packaging, and labelling. Addition of a second site of Dymax Corporation to the list of significant subcontractors with the service of manufacture. Removal of Romedex International SRL and SC Biosintex SRL from the list of significant subcontractors. Minor updates to subcontractors' addresses to reflect information included in vendors' certificates.
22 February 2019	7780646	Traceable to NB 0086.

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Date	Reference Number	Action
01 February 2020	9750254	Certificate renewal. Clarification of scope (wording update and addition of extension sets, remote control covers, ultrasounds system accessories, skin prep pads and catheter stabilization devices). Addition of supplementary information table. Removal of subcontractors 'Bard Limited, Crawley', 'Dymax Corporation, Warrendale' and 'Jiangyin PureMED Products Co, Ltd, Jiangyin City'. Addition of subcontractors 'BD Switzerland Sàrl, Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland', 'Advantech Corporation, 380 Fairview Way, Milpitas, CA 95035, USA', 'Exact Medical Manufacturing, Inc., No. 21 Qingjiang Road, Xinbei District, 213000 Changzhou, Jiangsu Province, People's Republic of China' and 'Zien Medical Technologies, 2757 South 300 West, STE F, Salt Lake City, UT 84115, USA'. Clarification of subcontractor's name (C.R. Bard, Inc. to Bard Medical Division).
Current	3290799	Clarification of scope to remove 'the accuracy of'. Formatting of supplementary information table, including removal of Class III and Class IIb rows (no device in scope). Correction of typo (MD0106 to MD 0106).
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
07 June 2022	3623482	Change in EU Representative from "BD Switzerland Sarl" to "Becton Dickinson Ireland Limited".

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Date	Reference Number	Action
10 June 2025	30432944	Scope reduced to remove extension sets, injection caps, gauzes, sponge sticks, drapes, scissors, clamps, flushing hubs, threader stylets, syringes, surgeon gowns, absorbent towels, forceps, measuring tapes, transparent dressings, tourniquets, surgeon caps, gloves, masks, remote control covers, catheter tracking device accessories, ultrasound system accessories, skin prep pads, and stoma measuring devices. The Class IIa Surgical Accessories (extension sets and injection caps), Site-Rite Prevue Ultrasound System, and Class Is Port and Catheter Placement Accessories, Catheter Accessories, Feeding Accessories, Catheter Tracking Accessories (including ECG Lead (Fin) Assembly, Sensor Holder, 12" Remote Control Cover, ECG Electrodes, and Elastic Bands), Nautilus Adaptors (ECG lead wires), and Ultrasound System Accessory, and Class Is/Im Stoma Measuring devices are removed from the device table.

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Inspiring trust for a more resilient world.

10 June 2025

Bard Access Systems, Inc.
605 North 5600 West
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

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) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 551349	93/42/EEC Annex V	30432944	Scope reduced to remove extension sets, injection caps, gauzes, sponge sticks, drapes, scissors, clamps, flushing hubs, threader stylets, syringes, surgeon gowns, absorbent towels, forceps, measuring tapes, transparent dressings, tourniquets, surgeon caps, gloves, masks, remote control covers, catheter tracking device accessories, ultrasound system accessories, skin prep pads, and stoma measuring devices. The Class IIa Surgical Accessories (extension sets and injection caps), Site-Rite Prevue Ultrasound System, and Class Is Port and Catheter Placement Accessories, Catheter Accessories, Feeding Accessories, Catheter Tracking Accessories (including ECG Lead (Fin) Assembly, Sensor Holder, 12"

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			Remote Control Cover, ECG Electrodes, and Elastic Bands), Nautilus Adaptors (ECG lead wires), and Ultrasound System Accessory, and Class Is/Im Stoma Measuring devices are removed from the device table.

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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