

EC Certificate - Full Quality Assurance System

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

No.

CE 597920

Issued To:

**Yukon Medical, LLC
4021 Stirrup Creek Drive
Suite 200
Durham
North Carolina
27703
USA**

In respect of:

The design, manufacture and final inspection of sterile needle-less luer valves for fluid drug administration, sterile access devices and connectors for reconstitution and transfer of drugs and sterile administration sets for connection to IV, intramuscular, intravesical and subcutaneous lines for administration of drugs, including as a closed system. Those aspects of Annex II concerned with securing and maintaining sterile conditions of single-use specimen collection devices and access devices, spikes, adapters and connectors for transfer, reconstitution and administration of drugs.

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: **2013-07-21**

Date: **2021-04-28**

Expiry Date: **2023-07-20**

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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 597920

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Number	Device Sub-Category	Intended purpose per IFU
Class IIa		
MD 0102	Needle-less closed male and neutral female luer valves	---
MD 0102	Closed vial adapter	---
MD 0102	Dry spike access device	---
MD 0102	Spike adapter with closed male luer (CML)	---
Class Is		
MD 0102	Vial access devices	---
MD 0102	Infusion access devices	---
MD 0102	Connectors	---
MD 0106	Specimen collection 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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
GILERO, LLC 635 Davis Drive Suite 100 Morrisville North Carolina 27560 USA	Design Manufacture
GILERO, LLC 158 Credle Street Pittsboro North Carolina 27312 USA	Assembly Packaging

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Subcontractor:	Service(s) supplied
Industrie Borla S.p.A Via Giuseppe di Vittorio, 7 bis Moncalieri-Torino 10024 Italy	Manufacture
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	Radiation (Gamma Sterilization)
Robling Medical, Inc. 90 Weathers Street Youngsville North Carolina NC 27596 USA	Manufacture

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Date	Reference Number	Action
21 July 2013	7974588	First issue.
09 October 2014	8194571	Update of address to 4021 Stirrup Creek Drive.
17 January 2017	8650274	Addition of IV infusion access devices.
16 June 2017	8681950	Addition of closed male luer device. Addition of significant subcontractors - Gilero with scope of Design and Industrie Borla S.P.A with scope of manufacture. Updated address for EU representative.
24 August 2017	8780719	Extension of scope to include Needle-less neutral valves and change of sterilization site name.
22 August 2018	8998817	Certificate renewal. Subcontractor activity added to EG-Gilero.
13 March 2019	9719486	Certificate update to correct devices and GMDN codes listed on supplementary information page. Administrative update to certificate scope to include generic scope wording for the class I sterile devices.
13 March 2019	9719688	Traceable to NB 0086.

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Date	Reference Number	Action
12 February 2020	3095583	Re-classification and extension to scope to include closed vial adapter, spike adapter with CML and dry spike as class IIa devices. Update to product supplementary page to reflect additional class IIa devices. Correction to post code for Industrie Borla S.p.A.
Current	3373703	Extension to scope to include class Is specimen collection devices. Update to supplementary information table to include specimen collection devices. Addition of GILERO Pittsboro as significant sub-contractor. Update to company name for GILERO Morrisville from GILERO, LLC d.b.a. EG GILERO to GILERO, LLC. Removal of GMDN codes from supplementary information table.

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