



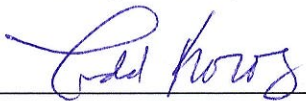
YUKON MEDICAL, LLC • 4021 Stirrup Creek Dr, Suite 200 • Durham • NC 27703 • 919.595-8250 • 919.595-8251 Fax
www.YukonMedical.com

DECLARATION OF CONFORMITY

Device Name	Universal SmartSite™ Vented Vial Access Device
Device Name/Type:	<ul style="list-style-type: none">• MV0400-0006 (458519) – FFS• MV040010-0006 (458819) – Multipack• MV040025-0006 (458719) – Multipack XL
Device Class/Rule:	Class 1 Sterile / Rule 2
GMDN Code:	58510 – Vial Transfer Spike
Legal Manufacturer:	Yukon Medical, LLC 4021 Stirrup Creek Drive, Suite 200 Durham, NC 27703
Contract Manufacturer:	Robling Medical, Inc. 90 Weathers Street Youngsville, NC 27596
Authorised Representative:	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands +31.70.345.8570 - phone
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands ID # 2797

I hereby declare that Yukon Medical, LLC (legal manufacturer) has fulfilled the obligations imposed by Annex II, Section 3.2 of the Medical Device Directive 93/42/EEC and the Universal SmartSite™ Vented Vial Access Device conforms to the Essential Requirements detailed in Annex 1 of the Medical Device Directive.

Full Quality Assurance Certificate (Annex II): British Standards Institution; No. CE 597920

Authorized Signatory: 
Todd Korogi, President and CEO

Date: June 27, 2019