Lake Region MEDICAL

DECLARATION OF CONFORMITY

Legal Manufacturer Name	Brivant Ltd
Legal Manufacturer Address	Parkmore West Business Park Galway Ireland
Manufacturing Site Name	BRIVANT Limited trading as Lake Region Medical International Research and Development Centre
Manufacturing Site Address	Parkmore West Business Park, Galway, Ireland
Device Name	CPS Courier Guidewire
Catalogue Numbers	

Part Number	Description
60016426-005	CPS Courier Guidewire, Extra Firm, Straight 005
60016426-010	CPS Courier Guidewire, Extra Firm, J Tip 010
60016426-004	CPS Courier Guidewire, Firm, Straight 004
60016426-009	CPS Courier Guidewire, Firm, J-Tip 009
60016426-003	CPS Courier Guidewire, Medium, Straight 003
60016426-008	CPS Courier Guidewire, Medium, J-Tip 008
60016426-002	CPS Courier Guidewire, soft, Straight 002
60016426-007	CPS Courier Guidewire, soft, J-Tip 007
60016426-001	CPS Courier Guidewire, Extra Soft, Straight 001
60016426-006	CPS Courier Guidewire, Extra soft, J-Tip 006

Device Classification	Class III
Declaration	I, the undersigned, hereby declare that the medical devices specified above meet the Essential Requirements listed in Annex 1 of Medical Device Directive 93/42/EEC
Reference Documentation	This Declaration is supported by: • EC Design Examination Certificate, certificate number 252.569, issued for the devices named above by National Standards Authority of Ireland. • EC-Quality System Approval Certificate number 252.569 issued by the National Standards Authority of Ireland according to Annex II of the Medical Device Directive 93/42/EEC, demonstrated by compliance to EN ISO 13485:2016.
Signed By	Clare Bowens-Reutter
Print Name	Clare Bowens-Reutter
Position	Quality & Regulatory Affairs Manager
Date	2 March 2020