

EU DECLARATION OF CONFORMITY to MEDICAL DEVICE REGULATION 2017/745		
Manufacturer Name:	Stryker Instruments	
Manufacturer Single Registration Number (SRN):	TBD	
Manufacturer Address:	1941 Stryker Way Portage, MI 49002 USA	
EU Authorized Representative Information:	Stryker European Operations Limited Anngrove, IDA Business & Technology Park Carrigtwohill, Co. Cork T45 HX08 Ireland	
See Appendix A for Device information.		
<p>We hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Device Regulation 2017/745.</p> <p>Each of the listed and CE Marked products in Appendix A has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulation 2017/745 prior to being placed on the market. This Declaration of Conformity is valid in conjunction with the respective production release records for the referenced devices. This declaration applies to CE Marked devices produced on or after the date issuance of this declaration and until it is superseded by another declaration or withdrawn.</p>		
Name and Identification Number of Notified Body	Description of Conformity Assessment Procedure	Issued Certificate Number
TÜV Rheinland 0197	Annex IX, Chapters I, III & Chapter II (sampling) of Regulation (EU) 2017/745	HZ 2247538-1
Reference to Common Specifications		
		Not applicable
Additional Information		
		Not applicable

Reviewed and Approved By	Brittney Larsen
Function:	Regulatory Affairs Manager
Place of Issue:	Portage, MI, USA
Date of Issue:	01-Mar-2021
Signature:	 <small>Electronically signed by: Brittney Larsen Reason: I approve this document Date: Mar 1, 2021 09:38 EST</small>

Appendix A: Device Information

Product Number	Product/ Accessory Trade Name	Basic UDI-DI	Device (Risk) Class	Intended Purpose	GMDN / CND Code	CE TD Number	Initial CE Release Date
Flyte Togas – Pullover:							
0408-720-000	Flyte Pullover Toga, Large	088582510024 36ST	Is	The Stryker Flyte Pullover Togas are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte Pullover Togas are sterile, single use only.	GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-730-000	Flyte Pullover Toga, X-Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-740-000	Flyte Pullover Toga, 2X Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-750-000	Flyte Pullover Toga, 3X Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
Flyte Togas – Zippered:							
0408-820-000	Flyte Zippered Toga, Large	088582510024 36ST	Is	The Stryker Flyte Zippered Togas are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte Zippered Togas are sterile, single use only.	GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-830-000	Flyte Zippered Toga, X-Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-840-000	Flyte Zippered Toga, 2X Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-850-000	Flyte Zippered Toga, 3X Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
Flyte Togas – Zippered PeelAway:							
0408-820-100	Flyte Toga, Peel-Away, Large	088582510024 36ST	Is	The Stryker Flyte Zippered Togas are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte Zippered Togas are sterile, single use only.	GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-830-100	Flyte PeelAway Toga, X-Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009
0408-840-100	Flyte PeelAway Toga, 2X Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb- 2009

0408-850-100	Flyte PeelAway Toga, 3X Large	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	13-Feb-2009
Flyte Hoods:							
0408-800-000	Flyte Hood	088582510024 36ST	Is	The Stryker Flyte Hoods are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte Hoods are sterile, single use only.	GMD: 35091 CND: T0204	TD-055	13-Feb-2009
0408-800-100	Flyte Hood, Peel-Away	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	18-Aug-2009
0408-800-400	Flyte Hood	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	30-Jan-2015
0408-800-500	Flyte Hood, Peel-Away	088582510024 36ST	Is		GMD: 35091 CND: T0204	TD-055	20-Jan-2015
Flyte SurgiCool Togas – Pullover:							
0408-721-000	Flyte SurgiCool Pullover Toga, Large	088582510024 35SR	Is	The Stryker Flyte SurgiCool Pullover Togas are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte SurgiCool Pullover Togas are sterile, single use only.	GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-731-000	Flyte SurgiCool Pullover Toga, X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-741-000	Flyte SurgiCool Pullover Toga, 2X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-751-000	Flyte SurgiCool Pullover Toga, 3X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
Flyte SurgiCool Togas – Zippered:							
0408-821-000	Flyte SurgiCool Zippered Toga, Large	088582510024 35SR	Is	The Stryker Flyte SurgiCool Zippered Togas are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and	GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-831-000	Flyte SurgiCool Zippered Toga, X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-841-000	Flyte SurgiCool Zippered Toga, 2X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015

0408-851-000	Flyte SurgiCool Zippered Toga, 3X Large	088582510024 35SR	Is	particulate material. The Flyte SurgiCool Zippered Togas are sterile, single use only.	GMD: 35091 CND: T0204	TD-148	30-Jan-2015
Flyte SurgiCool Togas - Zippered Peel Away:							
0408-821-100	Flyte SurgiCool Zippered Toga, Peel Away, Large	088582510024 35SR	Is	The Stryker Flyte SurgiCool Zippered Togas are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte SurgiCool Zippered Togas are sterile, single use only.	GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-831-100	Flyte SurgiCool Zippered Toga, Peel Away, X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-841-100	Flyte SurgiCool Zippered Toga, Peel Away, 2X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-851-100	Flyte SurgiCool Zippered Toga, Peel Away, 3X Large	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
Flyte SurgiCool Hoods:							
0408-801-400	Flyte SurgiCool Hood	088582510024 35SR	Is	The Stryker Flyte SurgiCool Hoods are components of the Stryker Personal Protection System and are intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Flyte SurgiCool Hoods are sterile, single use only.	GMD: 35091 CND: T0204	TD-148	30-Jan-2015
0408-801-500	Flyte SurgiCool Peel Away Hood	088582510024 35SR	Is		GMD: 35091 CND: T0204	TD-148	30-Jan-2015
<end>							

Appendix B: Revision History

Revision	Description of Change	Date
AA	Initial release of EU MDR DoC.	See onePLM
AB	Addition of CND codes and TUV Certificate number	See onePLM







DoC-D0000023094 MDR Flyte SurgiCool Hoods and Togas_Rev AB

Final Audit Report

2021-03-01

Created:	2021-03-01
By:	Corinne Larke (corinne.larke@stryker.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA8GNkpWTwkkOxoicFOX3W_kzmp7sS6jD5

"DoC-D0000023094 MDR Flyte SurgiCool Hoods and Togas_Rev AB" History

-  Document created by Corinne Larke (corinne.larke@stryker.com)
2021-03-01 - 2:24:23 PM GMT- IP address: 50.224.150.146
-  Document emailed to brittney larsen (brittney.larsen@stryker.com) for signature
2021-03-01 - 2:33:02 PM GMT
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2021-03-01 - 2:34:13 PM GMT- IP address: 52.154.71.15
-  brittney larsen (brittney.larsen@stryker.com) verified identity with Adobe Sign authentication
2021-03-01 - 2:38:27 PM GMT
-  Document e-signed by brittney larsen (brittney.larsen@stryker.com)
Signature Date: 2021-03-01 - 2:38:27 PM GMT - Time Source: server- IP address: 52.154.71.15
-  Agreement completed.
2021-03-01 - 2:38:27 PM GMT