

MDR Declaration of Conformity

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable General Safety & Performance Requirements in Annex 1
- Restriction of Hazardous Substances Directive (RoHS 3) (EU Directive 2015/863)

Common Specifications Applied:	Not Applicable
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Kaynesplein 9 1066 EP Amsterdam The Netherlands 2797
Supporting Certificate(s):	EU TDAC: MDR 758655 EU Quality Management System Certificate: MDR 758373
Original CE Mark Date:	1996
Conformity Assessment:	Annex IX

The products in the attached Declaration of Conformity Product List are approved under EC Certificate MDR 758373.

Declaration of Conformity Product List

Model No.	Product Trade Name	Basic UDI-DI
401575	Livewire™ Steerable Electrophysiology Catheter	5414734DMS0008J3
401904		
401905		
401908		
401914		
401915		
401932		
402032		