



EU DECLARATION OF CONFORMITY (DoC)

Product Family: HQ-19 - ShockPulse SE and CyberWand Systems
Product codes: Refer to Attachment 1
Product classification: Refer to Attachment 1

Manufacturer: Gyrus ACMI
9600 Louisiana Ave. North,
Brooklyn Park, MN 55445 USA

**Other facilities/
subcontractors:** Nissha Medical Technologies
93 N. Pleasant Street
Norwalk, OH 44857 USA
Gyrus ACMI, Inc.
9600 Louisiana Ave North
Brooklyn Park, MN 55445

Authorized Rep: OLYMPUS EUROPA SE & CO. KG
Wendenstraße 20, 20097 Hamburg, Germany
Postfach 10 49 08, 20034 Hamburg, Germany

CE marking: CE0344, DEKRA Certification B.V. Arnhem, The Netherlands

EC Certification No: 76997CE19

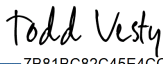
**Manufacturer’s single
registration number:** Pending

**The conformity with the
regulation is given by the
following standards:** Refer to tech file

This declaration is based on: 93/42/EEC of 14 June 1993 Council Directive, concerning medical devices. The application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EU-Medical Device Directive. The conformity assessment based on a quality management system and on assessment of technical documentation set out in Annex II. RoHs directive 2011/65/EU applies

We hereby declare that the distributed CE marked products, specified in the Device Listing, are in conformity with the Directive EU 93/42/EEC and covered by the "CE Marking of Conformity Certificate" or are self-declared as indicated in the product list. The devices meet the provisions of the EU regulations that apply to them based on the classification of the devices.

This declaration was issued under the sole responsibility of the manufacturer. This declaration is supported by the Quality Management System and certification based on the harmonized standard ISO 13485 Quality System Certificate issued by DEKRA Certification, B.V.

DocuSigned by:

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Apr-27-2023 | 8:42 AM EDT
Date of issue: _____
Signature: _____
Name: Todd Vesty
Title: Sr. Manager, Regulatory Affairs
Gyrus ACMI, Inc.
9600 Louisiana Ave. North,
Brooklyn Park, MN 55445 USA

Tech File: HQ-19

DOC Product List

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Item			Device Class	ROHS Applies	ROHS Compliant	ROHS Rationale	Actual Approval Date	Inactive Flag - Old	Inactive Date	Region
CW-RBPBX	CyberWand Probe Set,3/Box	CW-RBPBX	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	11-Jan-2016	N		European Union - Generic
CW-RBPBX	CyberWand Probe Set,3/Box	CW-RBPBX	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
CW-USLRBP	CYBERWAND RENA BLADDER PROBE	CW-USLRBP	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	11-Jan-2016	N		European Union - Generic
CW-USLRBP	CYBERWAND RENA BLADDER PROBE	CW-USLRBP	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-G	SHOCKPULSE LITHOTRIPSY GENERATOR	SPL-G	IIB	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-PDBX097	STERILE 0.97 SHOCKPULSE PROBE	SPL-PDBX097	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-PDBX097	STERILE 0.97 SHOCKPULSE PROBE	SPL-PDBX097	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-PDBX150	STERILE 1.50 SHOCKPULSE PROBE	SPL-PDBX150	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-PDBX150	STERILE 1.50 SHOCKPULSE PROBE	SPL-PDBX150	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-PDBX183	STERILE 1.83 SHOCKPULSE PROBE	SPL-PDBX183	IIA	Y	Y		04-May-2020	N		European Union - Generic
SPL-PDBX340	STERILE 3.40 SHOCKPULSE PROBE	SPL-PDBX340	IIA	Y	Y		31-Jul-2014	N		European Union - Generic
SPL-PDBX340	STERILE 3.40 SHOCKPULSE PROBE	SPL-PDBX340	IIA	Y	Y		04-May-2020	N		European Union - Generic
SPL-PDBX376	STERILE 3.76 SHOCKPULSE PROBE	SPL-PDBX376	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-PDBX376	STERILE 3.76 SHOCKPULSE PROBE	SPL-PDBX376	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-PR097	REUSABLE 0.97 SHOCKPULSE PROBE	SPL-PR097	IIA	Y	Y		31-Jul-2014	N		European Union - Generic
SPL-PR097	REUSABLE 0.97 SHOCKPULSE PROBE	SPL-PR097	IIA	Y	Y		04-May-2020	N		European Union - Generic
SPL-PR150	REUSABLE 1.50 SHOCKPULSE PROBE	SPL-PR150	IIA	Y	Y		31-Jul-2014	N		European Union - Generic
SPL-PR150	REUSABLE 1.50 SHOCKPULSE PROBE	SPL-PR150	IIA	Y	Y		04-May-2020	N		European Union - Generic
SPL-PR183	REUSABLE 1.83 SHOCKPULSE PROBE	SPL-PR183	IIA	Y	Y		31-Jul-2014	N		European Union - Generic
SPL-PR183	REUSABLE 1.83 SHOCKPULSE PROBE	SPL-PR183	IIA	Y	Y		04-May-2020	N		European Union - Generic
SPL-PR340	REUSABLE 3.40 SHOCKPULSE PROBE	SPL-PR340	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-PR340	REUSABLE 3.40 SHOCKPULSE PROBE	SPL-PR340	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-PR376	REUSABLE 3.76 SHOCKPULSE PROBE	SPL-PR376	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-PR376	REUSABLE 3.76 SHOCKPULSE PROBE	SPL-PR376	IIA	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-SR	SHOCKPULSE-SE LITHOTRIPSY SYSTEM (REUSABLE OPTION)	SPL-SR	IIB	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-SR	SHOCKPULSE-SE LITHOTRIPSY SYSTEM (REUSABLE OPTION)	SPL-SR	IIB	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic
SPL-T	SHOCKPULSE LITHOTRIPSY TRANSDUCER	SPL-T	IIB	Y	Y	FINISHED GOOD/OEM DEVICE	31-Jul-2014	N		European Union - Generic
SPL-T	SHOCKPULSE LITHOTRIPSY TRANSDUCER	SPL-T	IIB	Y	Y	FINISHED GOOD/OEM DEVICE	04-May-2020	N		European Union - Generic