

EG KONFORMITÄTSERKLÄRUNG / CE DÉCLARATION DE CONFORMITÉ CE DICHIARAZIONI DI CONFORMITÀ / EC DECLARATION OF CONFORMITY



**HAAG-STREIT
DIAGNOSTICS**

HAAG-STREIT AG
Gartenstadtstrasse 10
3098 Koeniz, Switzerland
CHRN-MF-20000022

EC REP

DE-AR-000009411

HAAG-STREIT Surgical GmbH & Co. KG
Rosengarten 10
22880 Wedel, Germany

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte
Nous déclarons sous notre propre responsabilité que les dispositifs médicaux
Dichiariamo sotto nostra propria responsabilità che i dispositivi medici
We declare under our sole responsibility that the medical devices

1803000 7220001

Perimeter OCTOPUS 900 Basic / Périmètre OCTOPUS 900 Basic / Perimeter OCTOPUS 900 Basic

der Klasse / de la classe della classe / of class	Ila	Regel / règle / regola / rule	10	von Anhang / de l'annexe / dell'allegato / of annex	IX
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allen Anforderungen der Richtlinien 93/42/EWG und 2011/65/EU entsprechen, welche anwendbar sind.
remplissent toutes les exigences les concernant des directives 93/42/CEE et 2011/65/UE.
rispondono a tutte le disposizioni che li riguardano delle direttive 93/42/CEE e 2011/65/UE.
meet all the provisions of the directives 93/42/EEC and 2011/65/EU which apply to them.

Angewandte harmonisierte oder internationale Normen Normes harmonisées ou internationales appliqués Norme armonizzate o internazionali applicate applicati Applied harmonised or international standards	EN 60601-1:2006 + A1:2013	Medical electrical equipment - General requirements for basic safety and essential performance
	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
	EN 62304:2006	Medical device software - Software life-cycle processes
	EN 62366:2008 + A1:2015	Medical devices - Application of usability engineering to medical devices
	EN 62471:2008	Photobiological safety of lamps and lamp systems
	EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
	EN ISO 12866:1999 + AC:2000 + A1:2008	Ophthalmic instruments - Perimeters
	EN ISO 15004-2:2007	Ophthalmic instruments - Fundamental requirements and test methods Part 2: Light hazard protection

Konformitätsbewertungsverfahren
Procédure d'évaluation de la conformité
Procedimento di valutazione della conformità
Conformity assessment procedure

Anhang
Appendice
Annesso
Annex

II

Konformitätsbewertungsstelle (falls beigezogen)
Organe responsable de l'évaluation de la conformité (si consulté)
Organo incarico della valutazione della conformità (se consultato)
Notified Body (if consulted)

DQS Medizinprodukte GmbH,
August-Schanz-Straße 21,
60433 Frankfurt am Main
Registration Number: 335325 MR2
CE label: CE 0297



Diese Konformitätserklärung ist gültig
Cette Déclaration de Conformité est valable
Questa Dichiarazione di Conformità è valida
This Declaration of conformity is valid

2021-05-24 - 2024-01-17

Koeniz, 2021-05-24

Place and Date of issue

Harald Müller
Head of Quality Management & Regulatory Affairs

Jörg Breitenstein
Head of Research & Development