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

HAAG-STREIT DIAGNOSTICS

HAAG-STREIT AG
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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 7220002

Perimeter OCTOPUS 900 Pro / Périmètre OCTOPUS 900 Pro / Perimeter OCTOPUS 900 Pro

der Klasse / de la classe della classe / of class	**IIa**	Regel / règle / regola / rule **10**	von Anhang / de l'annexe / dell'allegato / of annex **IX**

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