Declaration of Conformity - Contact Lenses Laser

Scope

This file contains all the Declarations of Conformity related to Contact Lens family of products. The following products are listed:

- Contact Lens Retina 145 L panfundus (1006092)
- Contact Lens 630 L universal short three mirrors (1400377)
- Contact Lens 903 L universal three mirrors (1400213)
- Contact Lens 906 L universal for babies three mirrors (1000421)
- Contact Lens 907 L universal for children three mirrors (1001577)
- Contact Lens CGAL goniscopy (1400421)
- Contact Lens CGIL iridectomy (1400427)
- Contact Lens CGPL capsulotomy (1400432)
- Contact Lens CGRL retina (1400442)
- Contact Lens CGVL vitrectomy (1400437)

Basic UDI-DI: 764013298LContact_LensCH

These devices are intended for:
The HAAG-STREIT Contact Lenses are a family of diagnostic and therapeutic contact lenses used in the examination of eye fundus, retina and irido-corneal and vitreous bodies and for the laser therapy of intraocular abnormalities.

Declaration of Conformity

Konformitätserklärung / Déclaration de Conformité / Dichiarazione di Conformità

We declare under our sole responsibility that the medical device
› *Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt*
› *Nous déclarons sous notre entière responsabilité que le dispositif médical*
› *Dichiariamo sotto nostra responsabilità che il dispositivo medico*

Contact Lenses Laser
Kontaktglas Laser
Verre de contact laser
Lente a contatto laser

of class
› *der Klasse*
› *de la classe*
› *della classe*
I

according to rule
› *gemäss Regel*
› *selon la règle*
› *secondo la regola*
5

following annex
› *nach Anhang*
› *selon l'annexe*
› *secondo l'allegato*
VIII

with part numbers
› *mit den Artikelnummern*
› *avec les numéros d'article*
› *con i numeri di posizione*

1001577, 1006092, 1000421, 1400213, 1400377, 1400421, 1400427, 1400432, 1400437, 1400442

meets all the provisions of the regulation 2017/745 (MDR) which apply. Compliance with the General Safety and Performance Requirements is achieved by application of international standards which have been listed in the document "Applied Standards".
› *alle geltenden Bestimmungen der Verordnung 2017/745 (MDR) erfüllt, die anwendbar sind. Die Einhaltung der Grundlegenden Sicherheits- und Leistungsanforderungen wird durch die Anwendung internationaler Normen erreicht, die im Begleitdokument "Applied Standards" aufgeführt sind.*
› *répondent à toutes les dispositions du règlement 2017/745 (MDR) qui s'appliquent. Le respect des Exigences Générales en Matière de Sécurité et de Performances est assuré par l'application des normes internationales énumérées dans le document annexe "Applied Standards".*
› *soddisfa tutte le disposizione della direttiva 2017/745 (MDR) che lo riguardano. La conformità ai Requisiti Generali di Sicurezza e Prestazioni si ottiene applicando gli standard internazionali elencati nel documento di accompagnamento "Applied Standards".*

Conformity Assessment Procedure
› *Konformitätsbewertungsverfahren*
› *Procédure d'évaluation de la conformité*
› *Procedura di valutazione della conformità*

Annex II+III

Manufacturer
› *Hersteller*
› *Fabricant*
› *Fabbricante*

HAAG-STREIT AG
SRN CH-MF-000020981
CHRN-MF-20000022
3098 Koeniz, Switzerland

Authorised Representative
› *Bevollmächtigter*
› *Mandataire*
› *Rappresentante autorizzato*

HAAG-STREIT Deutschland GmbH
SRN DE-AR-000025462
22880 Wedel, Germany

Notified Body
› *Konformitätsbewertungsstelle*
› *Organisme désigné*
› *Organismo notificato*

N/A

This Declaration of Conformity is valid until
› *Diese Konformitätserklärung gilt bis*
› *Cette Déclaration de Conformité est valable jusq'au*
› *Questa Dichiarazione di Conformità é valida fino al*

06/2025

CE **Köniz, 30.06.2022**
Place and Date of Issue

Eric Verstegen
Head of Quality Management and Regulatory Affairs

Jörg Breitenstein
Head of Research and Development