



Declaration of Conformity - Contact Lenses

Scope

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

- Contact Lens 630 universal short three mirrors (1400281)
- Contact Lens 901 macula (1400273)
- Contact Lens 902 gonioscopy one mirror (1400275)
- Contact Lens 902 S gonioscopy one mirror (1400276)
- Contact Lens 903 universal three mirrors (1400291)
- Contact Lens 903 S universal three mirrors (1400292)
- Contact Lens 903 without ring (1021993)
- Contact Lens 904 (1400349)
- Contact Lens 905 gonioscopy two mirrors (1400277)
- Contact Lens 905 S gonioscopy two mirrors (1400348)
- Contact Lens 906 universal for babies three mirrors (1400278)
- Contact Lens 906 S universal (1005840)
- Contact Lens 907 universal for children three mirrors (1400279)
- Contact Lens 907 without ring (1021994)
- Contact Lens 1210 endothelium (1021723)

Basic UDI-DI: 764013298Contact_Lens5M

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
Kontaktglas
Verre de contact
Lente a contatto

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

**1005840, 1021723, 1021993, 1021994, 1400273,
1400275, 1400276, 1400277, 1400278, 1400279,
1400281, 1400291 1400292, 1400348, 1400349**

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 disposizioni 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 jusqu'au
- › Questa Dichiarazione di Conformità è valida fino al

01/2028



Köniz, 31.01.2023
Place and Date of Issue

Eric Versteegen
Head of Quality Management and Regulatory Affairs

Jörg Breitenstein
Head of Research and Development