



## Declaration of Conformity MDR EU - Elara 900 VS

**Manufacturer** **Haag-Streit AG**  
SRN CH-MF-000020981  
CHRN-MF-20000022  
Gartenstadtstrasse 10, 3098 Koeniz, Switzerland

We declare under our sole responsibility that the product(s) listed to which this declaration relates, is in conformity with the applicable provisions of Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

**Device Group** Biomicroscope, Slit-lamp, AC-powered, Exempt (PUE)  
**Device Description** Elara 900 VS  
**Basic UDI-DI** 764013298ElaraQD

### Product Schedule

| REF     | Description  | Sales Number | EMDN      | GMDN  | UDI-DI         |
|---------|--------------|--------------|-----------|-------|----------------|
| 1421007 | Elara 900 VS | 7221085      | Z12120108 | 35148 | 07640132988925 |

**Intended Purpose** Elara is a digital slit lamp biomicroscope intended for use in eye examination. It is used to aid in the diagnosis and documentation of diseases or trauma which affect the structural properties of the eye.

**Risk Classification in accordance with Annex VIII** Class I

**Rule according Annex VIII** Rule 10

The General Safety and Performance Requirements is achieved by application of Common Specifications, Applied Standards and Guidance documents. These are available upon request.

**Conformity Assessment Procedure** Annex II+III

**EU Authorised Representative** **Haag-Streit Deutschland GmbH**  
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**Eric Verstegen**

Director Quality Management and Regulatory Affairs

**Jörg Breitenstein**

Director Research and Development

**Köniz, 28.04.2025**

Place and Date of Issue