

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



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

**EC REP**  
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

**1009000 7220096 7220376 7220400 1009001 7220460 7220494 7220497 7221015**

**Biometer LENSTAR LS 900**

**Biomètre LENSTAR LS 900**

**Biometer LENSTAR LS 900**

der Klasse / de la classe della classe / of class	<b>Ila</b>	Regel / règle / regola / rule	<b>10</b>	von Anhang / de l'annexe / dell'allegato / of annex	<b>IX</b>
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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	<b>EN 60601-1:2006 + A1:2013</b>	Medical electrical equipment - General requirements for basic safety and essential performance
	<b>EN 60601-1-2:2015</b>	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
	<b>EN ISO 15004-1:2009</b>	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
	<b>EN ISO 15004-2:2007</b>	Ophthalmic instruments - Fundamental requirements and test methods Part 2: Light hazard protection
	<b>EN 60825-1:2014</b>	Safety of laser products - Equipment classification and requirements
	<b>EN 62471:2008</b>	Photobiological safety of lamps and lamp systems

Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimento di valutazione della conformità Conformity assessment procedure	Anhang Appendice Annesso Annex	<b>II</b>
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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
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Diese Konformitätserklärung ist gültig Cette Déclaration de Conformité est valable Questa Dichiarazione di Conformità è valida This Declaration of conformity is valid	<b>2021-05-26 - 2024-01-17</b>
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Koeniz, 2021-06-07		
Place and Date of issue	Harald Müller Head Quality Management & Regulatory Affairs	Jörg Breitenstein Director Research & Development



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

### Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Ophthalmic Instruments according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	335325 MR2
Certificate unique ID	170769818
Effective date	2020-05-17
Expiry date	2024-01-17
Frankfurt am Main	2020-05-17

### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



**Annex to certificate**  
**Certificate registration No.: 335325 MR2**  
**Certificate unique ID: 170769818**  
**Effective date: 2020-05-17**



## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

Device family	Device	Class
Biometer	LENSTAR LS 900	Ila
	EYESTAR 900	Ila
Perimeter	OCTOPUS 900	Ila
	OCTOPUS 600	Ila
Tonometer	Applanation Tonometer AT 900D	Im
	Applanation Tonometer AT 900	Im
	Applanation Tonometer AT 870	Im
Sterile disposable attachment	Stery Cup Set	Is
Software	EyeSuite	Ila
	EyeSuite Imaging	Im

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

Date: 2023-12-19

### Notified Body Confirmation Letter Reference: 1000150460

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

SRN: CH-MF-000020981

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive. In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)





On behalf of the Notified Body

A handwritten signature in blue ink, appearing to read 'N. Wimmer'.

**Natalie Wimmer**  
Regulatory Affairs Manager



Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Biometer Lenstar:</b> <b>Biometer Lenstar LS 900 1009000</b> <b>Biometer Lenstar LS 900 APS 1009001</b>  <b>Basic UDI-DI:</b> <b>764013298LS9008S</b>	Class IIa	Biometer Lenstar LS 900	335325 MR2 Unique ID 170769818 NB 0297
<b>Biometer Eyestar 900 1021400</b>  <b>Basic UDI-DI:</b> <b>764013298ES9006D</b>	Class IIa	Biometer Eyestar 900	335325 MR2 Unique ID 170769818 NB 0297
<b>Perimeter Octopus 600 1806000</b>  <b>Basic UDI-DI:</b> <b>764013298O6008C</b>	Class IIa	Perimeter Octopus 600	335325 MR2 Unique ID 170769818 NB 0297
<b>Perimeter Octopus 900 1803000</b>  <b>Basic UDI-DI:</b> <b>764013298O9008T</b>	Class IIa	Perimeter Octopus 900	335325 MR2 Unique ID 170769818 NB 0297
<b>Applanation Tonometer AT 870 1420180</b>  <b>Basic UDI-DI:</b> <b>764013298AT8705Q</b>	Class I devices with a measuring function	Applanation Tonometer AT 870	335325 MR2 Unique ID 170769818 NB 0297
<b>Applanation Tonometer (analog) AT 900:</b> <b>Model BQ (1420152, 1420153, 1420156, 1420157)</b>	Class I devices with a measuring function	Applanation Tonometer AT 900D Applanation Tonometer AT 900	335325 MR2 Unique ID 170769818 NB 0297

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Model R (1420154) Model T (1420155)  Basic UDI-DI: 764013298AT900_D7A			

Table 2: Devices covered by this letter and for which the NB is **NOT** responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

#### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
19.12.2023	1000150460	Initial issue

# Agreement for continuation of MDD surveillance activities Regulation (EU) 2023/607

establishing the conditions for the continuation of the relevant surveillance activities pursuant to Article 120(3e) of Regulation (EU) 2017/745<sup>1</sup> in relation to legacy devices for which a certificate in accordance with Directive 93/42/EEC issued by DQS Medizinprodukte GmbH is available.

Upon signature by DQS Medizinprodukte GmbH, this application shall be deemed to be an Agreement for the performance of conformity assessment procedures between

<b>Company:</b> Name und legal form	Haag-Streit AG
<b>Address:</b> Street, house number Zip code, city Country	Gartenstadtstrasse 10 3098 Koeniz Switzerland
<b>Single Registration number (SRN):</b> <i>(acc. to Article 31)</i>	CH-MF-000020981
<b>Contact person:</b> Title, first name, last name	Mrs Kerrie Mouncey
<b>Telephone / Fax:</b>	+44 1279 456294
<b>E-Mail:</b>	kerrie.mouncey@haag-streit.com

- hereinafter referred to as "CERTIFICATION HOLDER" -,

and

**DQS Medizinprodukte GmbH**  
August-Schanz-Straße 21  
60433 Frankfurt am Main  
Deutschland

- hereinafter referred to as DQS MED -

The Agreement will be effective on **2023-11-14**.

<sup>1</sup> As extended by the Regulation (EU) 2023/607 of the European Parliament and of the Council dated 15<sup>th</sup> March 2023.



## § 1 Scope

1. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by DQS MED in accordance with Directive 93/42/EEC that is valid or to be considered to be valid by virtue of paragraph 2 of Article 120 Regulation (EU) 2017/745 covering a device which is placed on the market after date of application of the Regulation (EU) 2017/745 until the date set out in paragraph 3a of Article 120 of this Regulation (hereinafter referred to as "legacy device"<sup>2</sup>) that is subject to appropriate surveillance activities in respect of the applicable requirements according to Article 120 (3e) of Regulation (EU) 2017/745 (hereinafter referred to as "appropriate surveillance"), and intends that this appropriate surveillance in respect of that legacy device are continued to be carried out by DQS MED. Appropriate surveillance<sup>3</sup> can include for example documentation review, audits or other kinds of assessments respect of a legacy device (see § 6 (1)) as part of DQS MED's conformity assessment procedure under Regulation (EU) 2017/745. Certification is a valid confirmation in the form of a certification document, in accordance with Directive 93/42/EEC, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by DQS MED<sup>4</sup>.
2. The legacy devices that DQS MED issued a certification for and which are subject for continued appropriate surveillance are specified in Appendix 1.
3. Appropriate surveillance may be continued only in respect of a legacy device for as long as it is included in the scope of a certification considered as valid in accordance with Article 120 paragraph 2 or Regulation (EU) 2017/745 and issued by DQS MED covered with the respective designation/notification valid at the time when the certification was issued.

Certification, which is suspended or temporarily restricted for the relevant legacy device may not be accepted for continued appropriate surveillance in respect of that device.

Certification, which is withdrawn or otherwise invalidated is not subject to continued appropriate surveillance in respect of that device.

4. DQS MED has to ensure that adequate rights and obligations are agreed with CERTIFICATION HOLDER on a contractual basis to ensure the performance of appropriate surveillance incl. the right to suspend, restrict, withdraw etc. concerned certificates and are subject to this

<sup>2</sup>As per MDCG 2021-25 (Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021))

<sup>3</sup>As per MDCG 2022-4 rev. 1 (Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR regarding devices covered by certificates according to the MDD or the AIMDD (December 2022)):

Examples of surveillance activities (non-exhaustive):

- QMS audits
- focused audits (e.g. sterilization, microbiology, supplier etc.)
- unannounced audits
- for cause audits
- change notification assessment, e.g. changes which are considered not to be significant as per Art. 120.3
- Vigilance handling
- appeals
- complaints
- authority notes (e.g. CEFs, classification disputes/decisions)
- certificate actions: withdrawal, suspension, re-instatement, cancellations
- notification to national authorities

<sup>4</sup>According to section 4.3 of MDCG 2020-3 rev. 1 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023))

agreement; this includes as well auditing rights e.g. on the premises of CERTIFICATE HOLDER and his subcontractors etc.

5. The appropriate surveillance is governed by the terms set out in a certification agreement between CERTIFICATION HOLDER and DQS MED.
6. This Agreement specifies the terms and modalities for the continuance of appropriate surveillance by DQS MED in accordance with the Regulation (EU) 2017/745 and other relevant scheme requirements and ensures the continuity of the activities in accordance with this Regulation and requirements. The appropriate surveillance should be continued in accordance with the applicable requirements of provisions referenced at the end of this Agreement.

## **§ 2 Agreement conclusion and amendments**

The continuance of appropriate surveillance in accordance with this Agreement shall be accomplished in the following steps:

1. (Step 1). The appropriate surveillance process starts with the conclusion of this Agreement, including Appendix 1.
  - a. CERTIFICATION HOLDER signs the Agreement. The Agreement shall include Appendix 1. CERTIFICATION HOLDER then forwards the Agreement to DQS MED.
  - b. DQS MED verifies and countersigns the Agreement and returns it to CERTIFICATION HOLDER. At this time, any unclarities in the description of appropriate surveillance subject to transfer shall be resolved between the DQS MED and CERTIFICATION HOLDER, and corrections to the Agreement made, as necessary.
2. (Step 2). As soon as DQS MED's activities have progressed sufficiently in order to complete information in Appendix 1, or if it becomes clear that any of this information is no longer correct, the information in Appendix 1 must be supplemented or updated by way of an addendum to this Agreement. The form provided in Appendix 2 should be used for such an addendum, and the signatures may be performed as described in paragraph 1 points a to c.

It is the responsibility of DQS MED to decide whether the continuance of appropriate surveillance is appropriate, what additional assessment activities are needed prior to assuming the responsibility for the appropriate surveillance, and whether they are sufficient to maintain the appropriate surveillance in the way to keep the certification valid in the meaning of § 3 (1).

## **§ 3 Validity of certification and notified body surveillance activities for the legacy devices subject to transfer of appropriate surveillance**

1. CERTIFICATION HOLDER shall comply with the requirements of Article 120 of Regulation (EU) 2017/745 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1.

2. DQS MED shall not suspend or withdraw the CERTIFICATION HOLDER's certification, in respect of legacy devices subject to continuance of appropriate surveillance specified in Appendix 1, for the only reason as a reaction to the notification that the CERTIFICATION HOLDER is requesting the continuance of appropriate surveillance in respect of a legacy device. The rights of DQS MED to suspend or withdraw certification subject to transfer according to its certification agreement with CERTIFICATION HOLDER remain unaffected.
3. Appropriate surveillance, performed by DQS MED, will be fully continued in respect of the legacy devices specified in Appendix 1.
4. CERTIFICATION HOLDER shall continue to apply the notified body identification number of DQS MED to legacy devices subject to continued appropriate surveillance.
5. CERTIFICATION HOLDER commits to inform DQS MED in writing of the dates when the placing on the market of the legacy devices subject to continued appropriate surveillance under the notified body surveillance activities has been discontinued within 30 days after discontinuation.

#### **§ 4 Assessment prior to continuing appropriate surveillance activities**

DQS MED has the full responsibility and authority for the decision, based on information provided by CERTIFICATION HOLDER and publicly available information regarding the extent of its assessment prior to continuing appropriate surveillance. In all cases, DQS MED shall ensure that there is an overview of all required assessment activities and their individual status of completion. Any identified unresolved concerns, findings, non-conformities, surveillance notes, etc. shall be addressed based on their criticality in the scheduling/planning of the consecutive appropriate surveillance activities.

#### **§ 5 Confidentiality and obligation to provide information**

In order to allow DQS MED to complete the assessment prior to continuing appropriate surveillance activities according to § 4 and to perform the appropriate surveillance after the TRANSFER DATE (see § 1):

1. CERTIFICATION HOLDER commits to provide on request to the INCOMING NB any relevant information relating to its quality management system. Such a request may include the quality manual and any other document required to allow verification of compliance with requirements laid out in MDR, Article 10 (9) to 10 (13) <sup>5</sup>.

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<sup>5</sup> Question 11 of Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (March 2023): *Which evidence does the manufacturer have to provide for having put in place a QMS in accordance with the MDR?*

Pursuant to Article 120(3c), point (d), MDR the manufacturer must put in place a QMS in accordance with Article 10(9) MDR no later than 26 May 2024. Manufacturers must draw up the documentation on its QMS, which needs to be part of the application for conformity assessment. Compliance with QMS-related requirements concerning post-market surveillance, market surveillance, vigilance and registration are part of the appropriate surveillance pursuant to Article 120(3e) MDR.

## § 6 Continued appropriate surveillance

1. Beginning from the date of the countersignature (see § 2 (1) b), DQS MED shall assume full responsibility for the notified body appropriate surveillance activities<sup>6</sup> for the legacy device subject to continued appropriate surveillance, including
  - a. any continuing conformity assessment activities
  - b. surveillance activities
  - c. post-certification monitoring and the assessment of the CERTIFICATION HOLDER's vigilance system with respect to the legacy device manufactured which is under the transferred appropriate surveillance, including NB's involvement in vigilance case assessments
  - d. communication with authorities in respect of the legacy device
  - e. continued assessment of changes to the device
  - f. continued assessment of changes for the related quality management system
  - g. issuance of written confirmations to supplement or correct information mentioned in the certification document that covers the legacy device<sup>7</sup> including restriction, suspension and withdrawal of the validity of certification for the legacy device.
2. CERTIFICATION HOLDER shall comply with any requirement to notify the relevant authorities about appropriate surveillance continued by DQS MED in regard to legacy devices.
3. Changes on the device list as per Appendix 1 of this Agreement: based on MDCG 2020-3, rev. 1, section 4.3.2.3, the following changes are considered as "*non-significant change*" towards MDR, Art. 120(3c):
  - Change in Specification/Labeling:
    - *change within the currently certified range (more narrow or detailed information), new article inside certified worst case or accepted bracket validations such as:*
      - o new screw variant within current range of lengths and diameter;*
      - o new catheter variant, with length and diameter within current range and worst case in sterilisation performance;*
      - o new stent lengths which are intermediate between the previously certified stent lengths.*

In respect of this agreement, it means that additional devices might be added under the scope of the MDD certificate. The addition of such additional devices is considered only possible if for the same devices or its substitute device<sup>8</sup> a formal application has been lodged with DQS MED and written agreement for the MDR conformity assessment conducted.

The responsibility and liability towards the initial certification of the certified range and accepted bracket validations lies with DQS MED.

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while the assessment of the compliance with the MDR of the entire QMS will be done by the notified body as part of its conformity assessment activities.

<sup>6</sup> According to MDCG 2022-4 rev. 1 (Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022))

<sup>7</sup> According to section 4.3 of MDCG 2020-3 rev. 1 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023))

<sup>8</sup> Question 10 of Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (March 2023): "What is the meaning of 'device intended to substitute that device'?"

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The responsibility and liability towards the assessment of the appropriateness of the change under Art. 120, and further appropriate surveillance including individual device traceability along the new conditions lies with DQS MED.

### **§ 7 Settlement and property rights**

1. CERTIFICATION HOLDER shall settle, in respect of the legacy device subject to continued appropriate surveillance, all outstanding invoices with DQS MED.
2. All documents provided by DQS MED and all documents (assessment reports, etc.) which were generated by DQS MED for the performance of appropriate surveillance, in respect of the legacy device subject to continued appropriate surveillance, remain property of DQS MED.

### **§ 8 Miscellaneous**

1. (Severability). Should any individual provision of this Agreement or any part of any provision be or become void and/or unenforceable, the validity of the other provisions of the Agreement shall in no way be affected. In such case, the CERTIFICATION HOLDER and DQS MED shall replace, by way of an amendment or change to this Agreement, the void and/or unenforceable provisions with permissible provisions that fulfil the original intent of the void and/or unenforceable provision to the closest possible extent.
2. (Written form). Any amendments or changes to this Agreement shall be made in writing. The form provided in Appendix 2 should be used for such addendum.
3. (Liability). Each party is liable for the part of its contractual and legal duties. Especially DQS MED shall assume full responsibility for contracted surveillance activities with respect to all devices included in the scope of certification subject to continued appropriate surveillance.

DQS MED recognizes its responsibility for any act or omission. The CERTIFICATION HOLDER commits not to hold DQS MED responsible for these acts or omissions.

4. (Jurisdiction). Unless otherwise agreed, this Agreement shall be governed by, and interpreted in accordance with the substantive laws of the country of DQS MED exclusive of any rules with respect to conflicts of laws.
5. (Disputes). Disputes arising in connection with this Agreement shall be settled by CERTIFICATION HOLDER and DQS MED under the provisions of their certification agreement.
6. (Coming into force) This Agreement comes into force on the date DQS MED has signed this Agreement (also see § 6.1).



**Agreement for continuation of MDD surveillance activities  
Regulation (EU) 2023/607**



The parties confirm that information provided in this Agreement<sup>9</sup> and its Appendix 1 is correct and up-to-date to their best knowledge.

Agreed on behalf of CERTIFICATION HOLDER:

**Koniz, 11 Nov  
2023**

**Eric Verstegen**

Place, date

Name, Signature

Agreed on behalf of DQS MED:

**Bad Vilbel, 14  
Nov 2023**

**Natalie Wimmer**

Place, date

Name, Signature



Attached:

- Appendix 1 – Legacy devices subject to transfer of appropriate surveillance (mandatory)
- Appendix 2 – Addendum form to specify or amend Appendix 1 (optional)

<sup>9</sup> Overview of provisions covered or taken into consideration in this Agreement:

1. Articles 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC., as amended by Regulation (EU) 2023/607.
2. MDCG 2020-3 rev.1 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023))
3. MDCG 2022-4 rev.1 (Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022))
4. MDCG 2021-25 (Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021))
5. European Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (July 2023)

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Version: 3.0



Appendix 1 – Legacy devices subject to continued appropriate surveillance

Devices covered by this agreement and for which DQS MED (CE 0297) is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive.

MDD Device name or REF	MDD Certificate Reference(s) of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607) <sup>10</sup>	Imposed restrictions on the valid and not-suspended certificate or other relevant information	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is max. 6 months.
<b>Biometer Lenstar LS 900 1009000</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Biometer Lenstar LS 900 APS 1009001</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Biometer Eyestar 900 1021400</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Octopus 900 1803000</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Octopus 600 1806000</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>AT 900, Model BQ 1420152 1420153 1420156 1420157</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A

<sup>10</sup> Maximum transition timelines are defined as December 31<sup>st</sup> 2027 for class III and class IIb implantable devices, and December 31<sup>st</sup> 2028 for other class IIb, class IIa and class Is, Im and Ir devices.



Agreement for continuation of MDD surveillance activities  
Regulation (EU) 2023/607



AT 900 Model R 1420154	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
AT 900 Model T 1420155	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A



## Application Conformity Assessment QMS

Upon signature by DQS Medizinprodukte GmbH, this application is deemed to be a contract to conduct the conformity assessment procedures between

<b>Company:</b>	Haag-Streit AG
Name and legal form of the company	
<b>Address:</b>	Gartenstadtstrasse 10
Street, House No.	3098 Koeniz
ZIP Code, City	Switzerland
Country	
<b>Contact Person:</b>	Mrs Kerrie Mouncey
Title, First Name, Surname	
<b>Phone / Fax:</b>	+44 1279 456294
<b>E-Mail:</b>	kerrie.mouncey@haag-streit.com

- hereinafter referred to as APPLICANT -

and

**DQS Medizinprodukte GmbH**  
August-Schanz-Straße 21  
60433 Frankfurt am Main  
Deutschland

- hereinafter referred to as DQS MED -



**1 Conformity Assessment**

The APPLICANT hereby applies for the conduction of the below mentioned conformity assessment procedures:

---

**ISO 9001:2015 (DAkks<sup>1</sup>)**

Initial Certification       Re-Certification (Certificate-ID:      )

Description of the scope<sup>2</sup>:

---

**ISO 15378:2017 (DAkks<sup>1</sup>)**

Initial Certification       Re-Certification (Certificate-ID:      )

Description of the scope<sup>2</sup>:

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**DIN EN ISO 15378:2018 (DAkks<sup>1</sup>)**

Initial Certification       Re-Certification (Certificate-ID:      )

Description of the scope<sup>2</sup>:

---

**ISO 13485:2016 (SCC<sup>3</sup>)**

Initial Certification       Re-Certification (Certificate-ID:      )

Description of the scope<sup>2</sup>:

---

**(DIN EN) ISO 13485:2016 (DAkks<sup>1</sup>)**

Initial Certification       Re-Certification (Certificate-ID:      )

Description of the scope<sup>2</sup>:

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**ISO 13485:2016 (TCP III<sup>4</sup>)**

Initial Certification       Re-Certification (Certificate-ID:      )

Description of the scope<sup>2</sup>:

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<sup>1</sup> Certifications marked with „DAkks“ are carried out under accreditation of the German Accreditation Body (DAkks).

<sup>2</sup> The stated scope is a proposal that has to be verified during the audit and confirmed as part of the subsequent certification decision. The final scope is established using the information provided in the Basic Data and the List of Medical Devices.

<sup>3</sup> Certifications marked with „SCC“ are carried out under the accreditation of the Standards Council of Canada (SCC).

<sup>4</sup> ISO 13485 certification marked with „TCP III“ are carried out under the accreditation of the Technical Cooperation Programme Version 3.0 (TCP III) of the Taiwan Food and Drug Administration (TFDA).



- Medical Device Single Audit Program (MDSAP)**
  - Initial Certification
  - Re-Certification (Certificate-ID: )

The APPLICANT markets, or is planning to market, its medical devices to the following jurisdictions, and therefore has implemented the following applicable requirements:

- Australia:**
  - Therapeutic Goods (Medical Devices) Regulations 2002:
    - Schedule 3, Part 1 (excluding Part 1.6) - Full Quality Assurance System
    - Schedule 3, Part 4 - Quality Assurance System of Production
- Brazil:**
  - Federal Law n. 6,360/76
  - RDC ANVISA n. 665/ 2022 – Good Manufacturing Practices
  - RDC ANVISA n. 551/2021 – Mandatory Execution and Notification of Field Actions
  - RDC ANVISA n. 67/2009 – Vigilance
    - RDC ANVISA n. 56/2001 – Essential Requirements for Safety and Effectiveness
- Canada:**
  - Medical Device Regulations SOR/98-282, Part 1 RDC
- Japan:**
  - PMD Act
  - MHLW Ministerial Ordinance No.169, 2004 – Good Manufacturing Practices
- United States of America:**
  - 21 CFR Part 803 – Medical Device Reporting
  - 21 CFR Part 806 – Reports of Corrections and Removals
  - 21 CFR Part 807 (Subparts A to D) – Establishment Registration and Device Listing
  - 21 CFR Part 820 – Quality System Regulation
    - 21 CFR Part 821 – Device Tracking



- Regulation (EU) 2017/745**
- Initial Certification       Re-Certification <sup>5</sup> (Certificate-ID:      )

For the following conformity assessment procedures <sup>6</sup>:

- Annex IX Chapter I and III** <sup>7</sup>
- Annex XI Part A** <sup>7</sup>

With regard to devices already certified under Regulation (EU) 2017/745, it is requested:

- Transfer of Notified Body according to Article 58** <sup>8</sup>

With regards to the continuation of monitoring activities of medical devices previously CE marked according to MDD, the following is requested:

- Continuation of surveillance activities for MDD legacy devices according to Regulation (EU) 2023/607** <sup>9</sup>
- Transfer of surveillance activities for MDD legacy devices according to Regulation (EU) 2023/607** <sup>10</sup>

**Additional information concerning the conformation assessment procedures applied for (optional):**

Note: Depending on the requested conformity assessment activities, further information is required to be provided in supplementary forms Basic Data QMS and List of Medical Devices.

<sup>5</sup> The scope of the previous certification as well as the underlying sampling plan is continued. No new applications for product certification are required. If the previous scope is to be extended or restricted, please describe the change under "Additional information concerning the conformation assessment procedures applied for".

<sup>6</sup> Separate application forms are required for each conformity assessment procedure.

<sup>7</sup> For supplementary conformity assessments of products, further information is required in the form Transfer Agreement Application Conformity Assessment Product (420\_00).

<sup>8</sup> Further information is required in the supplementary form Transfer of Notified Body MDR (420\_01).

<sup>9</sup> Further information is required in the supplementary form Application for Continuation of MDD Surveillance Activities (420\_56).

<sup>10</sup> Further information is required in the supplementary form Transfer Agreement for Surveillance of Legacy Devices (420\_55).

## 2 Conformity Assessment - Changes

The APPLICANT hereby requests the following changes <sup>11</sup> to the following conformity assessment procedures:

<input type="checkbox"/> <b>ISO 9001:2015 (DAkks)</b>	Certificate-ID:
Description and details of the change:	
<input type="checkbox"/> <b>ISO 15378:2017 (DAkks)</b>	Certificate -ID:
Description and details of the change:	
<input type="checkbox"/> <b>DIN EN ISO 15378:2018 (DAkks)</b>	Certificate -ID:
Description and details of the change:	
<input type="checkbox"/> <b>ISO 13485:2016 (SCC)</b>	Certificate -ID:
Description and details of the change:	
<input type="checkbox"/> <b>(DIN EN) ISO 13485:2016 (DAkks)</b>	Certificate -ID:
Description and details of the change:	
<input type="checkbox"/> <b>ISO 13485:2016 (TCP III)</b>	Certificate -ID:
Description and details of the change:	
<input type="checkbox"/> <b>Medical Device Single Audit Program (MDSAP)</b>	Certificate -ID:
Description and details of the change:	
<input type="checkbox"/> <b>Regulation (EU) 2017/745 <sup>12 13</sup></b>	Certificate -ID:
<input type="checkbox"/> <b>Annex IX Chapter I and III <sup>14</sup></b>	
<input type="checkbox"/> <b>Annex XI, Part A <sup>14</sup></b>	
Description and details of the change:	

<sup>11</sup> A list of notifiable changes can be found in the General Business Conditions and the documents referenced therein.

<sup>12</sup> A separate application is required for each conformity assessment procedure.

<sup>13</sup> For changes regarding surveillance activities for MDD legacy devices, the forms Application for Continuation of MDD Surveillance Activities (420\_56) or Transfer Agreement for Surveillance of Legacy Devices (420\_55) are to be used.

<sup>14</sup> For changes to product conformity assessments, the form Application of Conformity Assessment Product (420\_00) is to be used.



Additional information concerning the conformation assessment procedures applied for (optional):

Note: Further information is required in the supplementary forms Basic Data QMS and List of Medical Devices.



**3 Contractual Provisions**

The following documents, including the additional documents referenced therein, are part of this contract to conduct the conformity assessment procedures and have been made available to the APPLICANT in the version valid at the time of application:

- General Business Conditions of DQS Medizinprodukte GmbH
- Auditing and Certification Regulations of DQS Medizinprodukte GmbH
- Assessment Services and Prices of DQS Medizinprodukte GmbH
- If conformity assessment according to MDSAP is requested: Supplement to the General Business Conditions of DQS Medizinprodukte GmbH applicable for auditing and certification under Medical Device Single Audit Program (MDSAP)
- If conformity assessment according to Regulation (EU) 2017/745 is requested: Supplement to the General Business Conditions of DQS Medizinprodukte GmbH applicable for auditing and certification under EU Regulation 2017/745

In the event of changes by DQS MED, the latest version made available to the APPLICANT at the time of application shall apply in each case. The APPLICANT acknowledges the validity of the listed documents in their respective valid version.

Additions, amendments or subsidiary agreements to this contract must be submitted in writing. In the event of invalidity of a single provision in this agreement, the validity of the remaining provisions shall not affect the validity of the remaining provisions. The invalid provision shall be replaced by a valid provision coming as close as possible to the original purpose.

The APPLICANT confirms with his signature that he has read and understood this certification contract as well as all documents listed above and accepts them as the basis of this contract. The APPLICANT confirms that all information provided by the APPLICANT in the application for certification and in the attached documents or correspondence is true and complete to the best of the APPLICANT's knowledge and belief.

By signing this document, the APPLICANT hereby applies to conduct the selected conformity assessment procedures. DQS MED shall perform the conformity assessment procedures in accordance with the contents of the contract.

Agreed on behalf of the APPLICANT:

Koniz, 19 Dec 2023    K. Mouncey   
Place, date                      Name, Signature



**Internal evaluation:**

*This section is for internal processing, please do not fill out.*

- |                                    |                                 |                                     |  |
|------------------------------------|---------------------------------|-------------------------------------|--|
| <input type="checkbox"/> Applicant | <input type="checkbox"/> CAP    | <input type="checkbox"/> Basic data | <input type="checkbox"/> Accr./Designation |
| <input type="checkbox"/> Signature | <input type="checkbox"/> Change | <input type="checkbox"/> List MD    | <input type="checkbox"/> Ressources        |

Agreed on behalf of DQS MED:

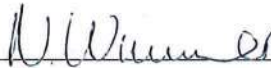
Frankfurt a.M.,  
21.12.2023

Place, date



i.A. N. Wimmer

Name, Signature



Appendix 2 – Addendum form to specify or amend Appendix 1

## Addendum No. 001 on Agreement for continuation of MDD surveillance activities came into force on 2023-12-19

between

Company:	Haag-Streit AG
Name and legal form	
Address:	Gartenstadtstrasse 10
Street name, house No.	3098 Koeniz Switzerland
ZIP-Code, City	
Country	
Registration No. (SRN): (according to Article 31)	CH-MF-000020981
Contact person:	Mrs Kerrie Mouncey
Title, First name, Surname	
Telephone / Fax:	+44 1279 456294
E-Mail:	kerrie.mouncey@haag-streit.com

- hereinafter referred to as APPLICANT -

and

DQS Medizinprodukte GmbH  
August-Schanz-Straße 21  
60433 Frankfurt am Main  
Deutschland

- hereinafter referred to as DQS MED –

The parties have agreed to amend the above-mentioned Agreement as follows in accordance with § 2 (2) and/or § 8 (2):

1. The table in Appendix 1 (Legacy devices subject to transfer of appropriate surveillance) is replaced with the following table:

MDD Device name or REF	MDD Certificate Reference(s) of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607) <sup>1</sup>	Imposed restrictions on the valid and notsuspended certificate or other relevant information	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is max. 6 months.
Biometer Lenstar: Biometer Lenstar LS 900 1009000 Biometer Lenstar LS 900 APS 1009001  Basic UDI-DI: 764013298LS9008S	170769818 335325MR2	<input checked="" type="checkbox"/> N/A  <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
Biometer Eyestar 900 1021400  Basic UDI-DI: 764013298ES9006D	170769818 335325MR2	<input checked="" type="checkbox"/> N/A  <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
Perimeter Octopus 600 1806000  Basic UDI-DI: 764013298O6008C	170769818 335325MR2	<input checked="" type="checkbox"/> N/A  <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
Perimeter Octopus 900 1803000  Basic UDI-DI: 764013298O9008T	170769818 335325MR2	<input checked="" type="checkbox"/> N/A  <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
Applanation Tonometer AT 870 1420180	170769818 335325MR2	<input checked="" type="checkbox"/> N/A  <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A

<sup>1</sup> Maximum transition timelines are defined as December 31<sup>st</sup> 2027 for class III and class IIb implantable devices, and December 31<sup>st</sup> 2028 for other class IIb, class IIa and class Is, Im and Ir devices.





Appendix 2 – Addendum form to specify or amend Appendix 1

# Addendum No. 001 on Agreement for continuation of MDD surveillance activities came into force on 2023-12-19

between

<b>Company:</b> Name and legal form	Haag-Streit AG
<b>Address:</b> Street name, house No. ZIP-Code, City Country	Gartenstadtstrasse 10 3098 Koeniz Switzerland
<b>Registration No. (SRN):</b> <i>(according to Article 31)</i>	CH-MF-000020981
<b>Contact person:</b> Title, First name, Surname	Mrs Kerrie Mouncey
<b>Telephone / Fax:</b>	+44 1279 456294
<b>E-Mail:</b>	kerrie.mouncey@haag-streit.com

- hereinafter referred to as APPLICANT -

and

**DQS Medizinprodukte GmbH**  
August-Schanz-Straße 21  
60433 Frankfurt am Main  
Deutschland

- hereinafter referred to as DQS MED -

The parties have agreed to amend the above-mentioned Agreement as follows in accordance with § 2 (2) and/or § 8 (2):

1. The table in Appendix 1 (Legacy devices subject to transfer of appropriate surveillance) is replaced with the following table:


MDD Device name or REF	MDD Certificate Reference(s) of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607) <sup>11</sup>	Imposed restrictions on the valid and not-suspended certificate or other relevant information	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is max. 6 months.
<b>Biometer Lenstar:</b> <b>Biometer Lenstar LS 900 1009000</b> <b>Biometer Lenstar LS 900 APS 1009001</b>  <b>Basic UDI-DI:</b> <b>764013298LS9008S</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Biometer Eystar 900 1021400</b>  <b>Basic UDI-DI:</b> <b>764013298ES9006D</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Perimeter Octopus 600 1803000</b>  <b>Basic UDI-DI:</b> <b>764013298O6008C</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Perimeter Octopus 900 1803000</b>  <b>Basic UDI-DI:</b> <b>764013298O9008T</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A
<b>Applanation Tonometer AT 870 1420180</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	N/A	N/A

<sup>11</sup> Maximum transition timelines are defined as December 31<sup>st</sup> 2027 for class III and class IIb implantable devices, and December 31<sup>st</sup> 2028 for other class IIb, class IIa and class Is, Im and Ir devices.


<b>Basic UDI-DI:</b> 764013298AT8705Q		device under MDR			
<b>Applanation Tonometer (analog) AT 900:</b> <b>Model BQ (1420152, 1420153, 1420156, 1420157)</b> <b>Model R (1420154)</b> <b>Model T (1420155)</b>	170769818 335325MR2	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> YYYY-MM-DD <input type="checkbox"/> 2027-12-31 <input checked="" type="checkbox"/> 2028-12-31	<b>N/A</b>	<b>N/A</b>
<b>Basic UDI-DI:</b> 764013298AT900_D7A					

The parties confirm that information provided in this ADDENDUM to the Application for continuation of MDD surveillance activities and its Appendix 1 is correct and up-to-date to their best knowledge.

Agreed on behalf of CERTIFICATION HOLDER:

Koniz, 19 Dec 2023    K. Mouncey   
 \_\_\_\_\_  
 Place, date                      Name, Signature

Agreed on behalf of DQS MED:

Bad Vilbel, 19.12.2023    i.A. N. Wimmer   
 \_\_\_\_\_  
 Place, date                      Name, Signature

Anexa 2 – Act adițional pentru detalierea sau modificarea Anexei 1

Actul Adițional nr. 001 la Contractul pentru  
continuarea activităților de supervizare MDD  
a intrat în vigoare la data de 19.12.2023

între

<b>Societatea:</b> Denumirea și forma legală	Haag-Streit AG
<b>Sediul:</b> Numele străzii, clădirea nr., cod poștal, oraș Țara	Gartenstadtstrasse 10 3098 Koeniz Elveția
<b>Număr înregistrare: (SRN):</b> (conform Articolului 31)	CH-MF-000020981
<b>Persoană de contact:</b> Funcție, Prenume, Nume	Mrs Kerrie Mouncey
<b>Telefon/Fax:</b>	+44 1279 456294
<b>E-Mail:</b>	kerrie.mouncey@haag-streit.com

- denumită în cele ce urmează SOLICITANTUL -

și

**DQS Medizinprodukte GmbH**  
August-Schanz-Straße 21  
60433 Frankfurt am Main  
Deutschland

- denumit în cele ce urmează DQS MED -

Părțile au convenit să modifice Contractul mai sus menționat după cum urmează, în conformitate cu § 2 (2) și/sau § 8 (2):

1. Tabelul din Anexa 1 (Dispozitive moștenite supuse transferului sau supervizării corespunzătoare) este înlocuit cu următorul tabel:

Denumirea sau Referința dispozitivului MDD	Referința Certificatului MDD pentru dispozitivul MDD	Dacă certificatul este înlocuit (substituit) conform MDR cu un alt dispozitiv – vă rugăm să identificați dispozitivul corespunzător de substituie	Programul maxim de tranziție conform Articolului 120.3c din MDR (după cum este modificat prin UE 2023/607) <sup>11</sup>	Restricțiile impuse asupra certificatului valid și nesuspendat sau alte informații relevante	PERIOADA convenită de LICHIDARE (a se vedea § 3 (4)) Dacă nu se specifică în mod explicit, PERIOADA DE LICHIDARE este de maximum 6 luni
<b>Biometru Lenstar:</b> <b>Biometru Lenstar LS 900 1009000</b> <b>Biometru Lenstar LS 900 APS 1009001</b> <b>UDI-DI de bază:</b> <b>764013298LS9008S</b>	170769818 335325MR2	<input checked="" type="checkbox"/> Nu se aplică <input type="checkbox"/> Identificare dispozitiv de substituie corespunzător conform MDR	<input type="checkbox"/> ZZ-LL-AAAA <input type="checkbox"/> 31.12.2027 <input checked="" type="checkbox"/> 31.12.2028	<b>NU SE APLICĂ</b>	<b>NU SE APLICĂ</b>
<b>Biometru Eyestar 900 1021400</b>  <b>UDI-DI de bază:</b> <b>764013298ES9006D</b>	170769818 335325MR2	<input checked="" type="checkbox"/> Nu se aplică <input type="checkbox"/> Identificarea dispozitivului de substituie corespunzător conform MDR	<input type="checkbox"/> ZZ-LL-AAAA <input type="checkbox"/> 31.12.2027 <input checked="" type="checkbox"/> 31.12.2028	<b>NU SE APLICĂ</b>	<b>NU SE APLICĂ</b>
<b>Perimetru Octopus 600 1803000</b>  <b>UDI-DI de bază:</b> <b>764013298O6008C</b>	170769818 335325MR2	<input checked="" type="checkbox"/> Nu se aplică <input type="checkbox"/> Identificarea dispozitivului de substituie corespunzător conform MDR	<input type="checkbox"/> ZZ-LL-AAAA <input type="checkbox"/> 31.12.2027 <input checked="" type="checkbox"/> 31.12.2028	<b>NU SE APLICĂ</b>	<b>NU SE APLICĂ</b>
<b>Perimetru Octopus 900 1803000</b>  <b>UDI-DI de bază:</b> <b>764013298O9008T</b>	170769818 335325MR2	<input checked="" type="checkbox"/> Nu se aplică <input type="checkbox"/> Identificarea dispozitivului de substituie corespunzător conform MDR	<input type="checkbox"/> ZZ-LL-AAAA <input type="checkbox"/> 31.12.2027 <input checked="" type="checkbox"/> 31.12.2028	<b>NU SE APLICĂ</b>	<b>NU SE APLICĂ</b>
<b>Tonometru de aplanție AT 870 1420180</b>	170769818 335325MR2	<input checked="" type="checkbox"/> Nu se aplică <input type="checkbox"/> Identificarea dispozitivului de substituie corespunzător	<input type="checkbox"/> ZZ-LL-AAAA <input type="checkbox"/> 31.12.2027 <input checked="" type="checkbox"/> 31.12.2028	<b>NU SE APLICĂ</b>	<b>NU SE APLICĂ</b>

<sup>11</sup> Programele maxime de tranziție sunt definite la 31 decembrie 2027 pentru dispozitivele implantabile de clasa III și de clasa IIb și 31 decembrie 2028 pentru alte dispozitive de clasa IIb, clasa IIa și clasa Is, Im și Ir.

<b>UDI-DI de bază:</b> 764013298AT8705Q		în conformitate cu MDR			
<b>Tonomtru de Aplanație (analog) AT 900</b> <b>Model BQ (1420152, 1420153, 1420156, 1420157)</b> <b>Model R (1420154)</b> <b>Model T (1420155)</b>  <b>UDI-DI de bază:</b> 764013298AT900_D7A	170769818 335325MR2	<input checked="" type="checkbox"/> Nu se aplică <input type="checkbox"/> Identificarea dispozitivului de substituire corespunzător în conformitate cu MDR	<input type="checkbox"/> ZZ-LL-AAAA <input type="checkbox"/> 31.12.2027 <input checked="" type="checkbox"/> 31.12.2028	<b>NU SE APLICĂ</b>	<b>NU SE APLICĂ</b>

Părțile confirmă faptul că informațiile furnizate în prezentul ACT ADIȚIONAL la Cererea de continuare a activităților de supervizare MDD și Anexa 1 sunt corecte și actualizate, după cunoștința acestora.

Convenit în numele DEȚINĂTORULUI CERTIFICATULUI:

Koniz, 19 decembrie 2023 K. Mouncey

Locul, data

Nume, Semnătură

Convenit în numele DQS MED:

Bad Vilbel, 19.12.2023

Locul, data

i.A. N. Wimmer

Nume, Semnătură

Subsemnatul **PAUL GHEORGHE**, interpret și traducător autorizat pentru limbile Portugheză, Spaniolă și Engleză, cu numărul de autorizație 9786/2007, eliberată de Ministerul Justiției din România, certific exactitatea traducerii efectuate din limba **Engleză** în limba română, că textul prezentat a fost tradus în întregime și că, prin traducere, înscrisului nu i-a fost denaturat conținutul și sensul.

Traducător autorizat  
**PAUL GHEORGHE**



## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

Date: 2023-12-19

### Notified Body Confirmation Letter Reference: 1000150460

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

SRN: CH-MF-000020981

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive. In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)



On behalf of the Notified Body,

A handwritten signature in black ink, appearing to read 'N. Wimmer'.

**Natalie Wimmer**  
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Biometer Lenstar:</b> <b>Biometer Lenstar LS 900 1009000</b> <b>Biometer Lenstar LS 900 APS 1009001</b>  <b>Basic UDI-DI:</b> <b>764013298LS9008S</b>	Class IIa	Biometer Lenstar LS 900	335325 MR2 Unique ID 170769818 NB 0297
<b>Biometer Eyestar 900 1021400</b>  <b>Basic UDI-DI:</b> <b>764013298ES9006D</b>	Class IIa	Biometer Eyestar 900	335325 MR2 Unique ID 170769818 NB 0297
<b>Perimeter Octopus 600 1803000</b>  <b>Basic UDI-DI:</b> <b>764013298O6008C</b>	Class IIa	Perimeter Octopus 600	335325 MR2 Unique ID 170769818 NB 0297
<b>Perimeter Octopus 900 1803000</b>  <b>Basic UDI-DI:</b> <b>764013298O9008T</b>	Class IIa	Perimeter Octopus 900	335325 MR2 Unique ID 170769818 NB 0297
<b>Applanation Tonometer AT 870 1420180</b>  <b>Basic UDI-DI:</b> <b>764013298AT8705Q</b>	Class I devices with a measuring function	Applanation Tonometer AT 870	335325 MR2 Unique ID 170769818 NB 0297
<b>Applanation Tonometer (analog) AT 900:</b> <b>Model BQ (1420152, 1420153, 1420156, 1420157)</b> <b>Model R (1420154)</b> <b>Model T (1420155)</b>  <b>Basic UDI-DI:</b> <b>764013298AT900_D7A</b>	Class I devices with a measuring function	Applanation Tonometer AT 900D Applanation Tonometer AT 900	335325 MR2 Unique ID 170769818 NB 0297

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

#### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
19.12.2023	1000150460	Initial issue

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Elveția

Data: 19.12.2023

### Scrisoare de confirmare a Organismului notificat Referință 1000150460

În atenția persoanelor interesate,

**Confirmare cu privire la statutul unei cereri oficiale, al unui acord scris și al unei supervizări adecvate în cadrul Regulamentului UE 2023/607 de modificare a Regulamentelor (UE) 2017/745 și (UE) 2017/746 în ceea ce privește dispozițiile tranzitorii pentru anumite dispozitive medicale și dispozitive medicale pentru diagnosticare in vitro.**

Prezenta scrisoare confirmă faptul că DQS Medizinprodukte GmbH, Organism notificat desemnat în conformitate cu Regulamentul (UE) 2017/745 (MDR) și identificat prin numărul 0297 în NANDO, a primit o cerere oficială, în conformitate cu Secțiunea 4.3, primul subparagraf din Anexa VII la MDR și a semnat un acord scris în conformitate cu secțiunea 4.3, al doilea subparagraf din Anexa VII la MDR cu producătorul de mai jos:

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Elveția

SRN: CH-MF-000020981

Dispozitivele acoperite de cererea oficială și acordul scris menționate mai sus sunt identificate în Tabelele de mai jos: Tabelul 1 prezintă dispozitivele pentru care s-a primit o cerere conform MDR, pentru care s-a încheiat un acord scris și pentru care DQS Medizinprodukte GmbH este, de asemenea, responsabil de supravegherea corespunzătoare, în conformitate cu Directiva aplicabilă. Tabelul 2 prezintă dispozitivele pentru care s-a primit o cerere conform MDR și pentru care s-a încheiat un acord scris, dar pentru care DQS Medizinprodukte GmbH nu și-a asumat încă responsabilitatea pentru supervizarea adecvată a dispozitivelor corespunzătoare, în conformitate cu Directiva aplicabilă. În cazul dispozitivelor care fac obiectul unor certificate emise în temeiul Directivei 90/385/CEE (AIMDD) sau al Directivei 93/42/CEE (MDD) care au expirat după data de 26 mai 2021, dar înainte de 20 martie 2023, fără să fi fost retrase, prezenta scrisoare confirmă, de asemenea, că producătorul fie a semnat acordul scris în temeiul MDR până la data expirării certificatului MDD/AIMDD; fie a furnizat dovezi că o autoritate competentă a unui stat membru a acordat o derogare sau o scutire de la procedura de evaluare a conformității aplicabilă în conformitate cu articolul 59, alineatul (1) din MDR sau, respectiv, cu articolul 97 alineatul (1) din MDR, până la 20 martie 2023 pentru dispozitivele relevante.

Termenele de tranziție care se aplică dispozitivelor care fac obiectul prezentei scrisori, sub rezerva respectării în continuare, de către producător, a celorlalte condiții specificate la articolul 120.3c din MDR (astfel cum a fost modificat prin Regulamentul (UE) 2023/607), sunt prezentate mai jos:

- 26 mai 2026 pentru dispozitivele implantabile la comandă de Clasa III
- 31 decembrie 2027 pentru dispozitivele din Clasa III și pentru dispozitivele implantabile din Clasa IIb, cu excepția tehnologiilor consacrate (WET: suturi, capse, plombe dentare, aparate dentare, coroane dentare, șuruburi, pene, plăci, sârme, ace, cleme și conectori)
- 31 decembrie 2028 pentru alte dispozitive din Clasa IIb, dispozitive din clasa IIa și clasa I introduse pe piață în condiții sterile sau care au o funcție de măsurare
- 31 decembrie 2028 pentru dispozitivele care nu necesită un Organism notificat în baza MDD, dar care necesită unul în baza MDR (de exemplu, dispozitive din clasa I care se califică drept instrumente chirurgicale reutilizabile)

În numele Organismului notificat,

A handwritten signature in blue ink, appearing to read 'N. Wimmer'.

**Natalie Wimmer**  
Director Afaceri de reglementare

**Tabel 1: Dispozitivele acoperite de prezenta scrisoare și pentru care Organismul notificat (ON) este, de asemenea, responsabil pentru supravegherea adecvată a dispozitivelor corespunzătoare, în temeiul Directivei aplicabile:**

Denumirea dispozitivului și UDI-DI de bază (așa cum au fost propuse de producător în cerere)	Clasificare dispozitive MDR (așa cum a fost propus de producător și verificat în etapa de cerere preliminară)	În cazul în care dispozitivul MDR este un dispozitiv de substituție, identificarea dispozitivului MDD/AIMDD corespunzător	Referința (referințele) Certificatului MDD/AIMDD al (ale) dispozitivelor care fac obiectul cererii MDR și identificarea ON
<b>Biometru Lenstar:</b> <b>Biometru LENSTAR LS 900 1009000</b> <b>Biometru LENSTAR LS 900 1009001</b>  <b>UDI-DI de bază:</b> <b>764013298LS9008S</b>	Clasa IIa	Biometru Lenstar LS 900	335325 MR2 ID unic 170769818 ON 0297
<b>Biometru Eyestar 900 1021400</b>  <b>UDI-DI de bază:</b> <b>764013298ES9006D</b>	Clasa IIa	Biometru Eyestar 900	335325 MR2 ID unic 170769818 ON 0297
<b>Perimetru OCTOPUS 600 1803000</b>  <b>UDI-DI de bază:</b> <b>764013298O6008C</b>	Clasa IIa	Perimetru Octopus 600	335325 MR2 ID unic 170769818 ON 0297
<b>Perimetru OCTOPUS 900 1803000</b>  <b>UDI-DI de bază:</b> <b>764013298O9008T</b>	Clasa IIa	Perimetru Octopus 900	335325 MR2 ID unic 170769818 ON 0297
<b>Tonometru de aplanatie AT 870 1420180</b>  <b>UDI-DI de bază:</b> <b>764013298AT8705Q</b>	Dispozitive de Clasa I cu funcție de măsurare	Tonometru de aplanatie AT 870	335325 MR2 ID unic 170769818 ON 0297
<b>Tonometru de aplanatie (analog) AT 900</b> <b>Model BQ (1420152, 1420153, 1420156, 1420157)</b> <b>Model R (1420154)</b> <b>Model T (1420155)</b>  <b>UDI-DI de bază:</b> <b>764013298AT900_D7A</b>	Dispozitive de Clasa I cu funcție de măsurare	Tonometru de aplanatie AT 900D Tonometru de aplanatie AT 900	335325 MR2 ID unic 170769818 ON 0297

**Tabel 2: Dispozitivele acoperite de prezenta scrisoare și pentru care organismul notificat NU este responsabil pentru supravegherea adecvată a dispozitivelor corespunzătoare în temeiul Directivei aplicabile:**

<b>Denumirea dispozitivului și UDI-DI de bază (așa cum au fost propuse de producător în cerere)</b>	<b>Clasificare dispozitive MDR (așa cum a fost propus de producător și verificat în etapa de cerere preliminară)</b>	<b>În cazul în care dispozitivul MDR este un dispozitiv de substituție, identificarea dispozitivului MDD/AIMDD corespunzător</b>	<b>Referința (referințele) Certificatului MDD/AIMDD al (ale) dispozitivelor care fac obiectul cererii MDR și identificarea ON</b>
Nu se aplică	Nu se aplică	Nu se aplică	Nu se aplică

**Istoricul revizuirilor scrisorii de confirmare**

<b>Data</b>	<b>Referința internă a ON care poate fi urmărită în fiecare versiune a scrisorii</b>	<b>Acțiune</b>
19.12.2023	1000150460	Versiune inițială

Subsemnatul **PAUL GHEORGHE**, interpret și traducător autorizat pentru limbile Portugheză, Spaniolă și Engleză, cu numărul de autorizație 9786/2007, eliberată de Ministerul Justiției din România, certifică exactitatea traducerii efectuate din limba **Engleză** în limba română, că textul prezentat a fost tradus în întregime și că, prin traducere, înscrisului nu i-a fost denaturat conținutul și sensul.

Traducător autorizat

**PAUL GHEORGHE**





# CERTIFICATE



This is to certify that the company

## Haag-Streit AG

Gartenstadtstrasse 10  
3098 Koeniz  
Switzerland

has implemented and maintains a **Quality Management System**.

### Scope:

Design and development, manufacturing, distribution, installation and servicing of mechanical, optical and electronic precision instruments including related software for ophthalmologic application.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## EN ISO 13485:2016 / A11 : 2021 ISO 13485 : 2016

Certificate registration no.	335325 MP2021
Certificate unique ID	1000194725
Effective date	2025-01-21
Expiry date	2028-01-20
Frankfurt am Main	2024-12-03



### DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director

DQS IS A MEMBER OF



August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [info-med@dqs.de](mailto:info-med@dqs.de)  
The validity of the certification can only be verified by the QR-code.

## Legalization of copy

**Philippe Frésard**

Notary of the Canton of Berne (Switzerland)  
registered in the notary register of the Canton of Berne, with office in Berne

*certifies:*

The present document is a true and complete copy of the electronic copy which was submitted to the Notary.

Certified at the office of the Notary, in Berne (Switzerland), on the twenty-fifth of February two thousand and twenty-five.

**D.d. 25/02/2025**

The Notary:



### Apostille

(Convention de La Haye du 5 octobre 1961)

1. Country: Swiss Confederation, Canton of Bern

This public document

2. has been signed by **Philippe Frésard**

3. acting in the capacity of **Notary**

4. bears the seal / stamp of  
**Notary of the canton of Bern**

Certified

5. at Bern 6. the 26/02/2025

7. by the State Chancellery of the canton of Bern

8. No. 2669 Tax CHF 25.00

9. Seal / Stamp 10. Signature

  
**Sarah Flückiger**



# CERTIFICAT

Se certifică faptul că compania

**Haag-Streit AG**

Gartenstadtstrasse 10  
3098 Koeniz  
Elveția

a implementat și menține un **Sistem de Management al Calității**.

**Domeniu de aplicare:**

Proiectarea și dezvoltarea, fabricarea, distribuția, instalarea și întreținerea instrumentelor de precizie mecanice, optice și electronice, inclusiv software asociat, pentru aplicații oftalmologice.

În urma unui audit, documentat într-un raport realizat de **DQS Medizinprodukte GmbH**, s-a verificat că sistemul de management îndeplinește cerințele standardului:

**EN ISO 13485:2016 / A11:2021**  
**ISO 13485:2016**

Număr înregistrare certificat: 335325 MP2021  
ID unic certificat: 1000194725  
Data intrării în vigoare: 21.01.2025  
Data expirării: 20.01.2028  
Frankfurt am Main: 03.12.2024



**DQS Medizinprodukte GmbH**

Heinrich von Mettenheim  
Director General  
*[semnătură olografă indescifrabilă]*

DQS ESTE MEMBRU AL IQNET  
*[Cod QR]*

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel.: +49 (0) 69 95427-300, [info-med@dqs.de](mailto:info-med@dqs.de)

**Valabilitatea acestui certificat poate fi verificată doar prin codul QR.**  
414.91e Versiunea 2.0

**Legalizarea copiei**

**Philippe Frésard**

Notar al Cantonului Berna (Elveția),  
înregistrat în registrul notarilor al Cantonului Berna, cu biroul în Berna,

*certifică:*

Prezentul document este o copie fidelă și completă a copiei electronice care a fost transmisă notarului.

Certificat la biroul notarului din Berna (Elveția), în data de douăzeci și cinci februarie două mii douăzeci și cinci.

**D.d. 25/02/2025**

Notarul:

Semnătura notarului: *[semnătură olografă indescifrabilă]*

Ștampilă Philippe Frésard

Notar al Cantonului Berna

### **Apostille**

(Convention de La Haye du 5 octobre 1961)

1. Țara: Confederația Elvețiană, Cantonul Berna  
Prezentul act oficial
2. a fost semnat de **Philippe Frésard**
3. În calitate de **Notar**
4. Poartă sigiliul/ștampila  
**Notar al Cantonului Berna**

ATESTAT

5. la Berna
  6. Data 26.02.2025
  7. de către Cancelaria de Stat a Cantonului Berna
  8. sub nr. 2669 Taxă: CHF 25.00
  9. Sigiliul/Ștampila
  10. Semnătura: **Sarah Flückiger**  
*[semnătură olografă indescifrabilă]*
- [Ștampilă oficială a Cancelariei de Stat a Cantonului Berna]*

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Subsemnata, **Iordache Anca-Elena**, interpret și traducător autorizat pentru limba engleză, în temeiul Autorizației nr. 38838 /2021, eliberată de Ministerul Justiției, certific exactitatea traducerii efectuate din limba engleză în limba română, că textul prezentat a fost tradus în integralitatea sa și că, prin traducere, înscrisului nu i-au fost denaturate conținutul și sensul.

Ministerul Justiției  
**Anca-Elena Iordache**  
Aut. Nr. 38838/2021  
Limba Engleză  
Traducător și Interpret Autorizat



**ANEXA din data 25.07.2025**  
**LA AVIZUL DE FUNCȚIONARE**  
**Nr. 5351/04.07.2024 al KEMBLI-MED SRL**  
**CUI 10511100, J1998000499081**

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate și a raportului de evaluare pentru cererea 47225/10.07.2025 care face parte integrantă din prezenta anexă, Avizul de funcționare nr. 5351/04.07.2024 se actualizează după cum urmează:

Operatorul economic este importator al producătorilor:

Nr crt	Nume producător	Țara
1	APTISSEN SA	Elveția
2	AUROLAB	India
3	BEAVER-VISITEC INTERNATIONAL INC.	SUA
4	CHONGQING IRC MEDICAL EQUIPMENT CO. LTD.	China
5	CHONGQING KANGHUARUIMING SCIENCE TECHNOLOGY CO.,LTD	China
6	CRYSTALVUE MEDICAL CORPORATION	Taiwan
7	DENT4YOU AG	Elveția
8	DIOPSYS INC.	SUA
9	EAGLE LABS, LLC	SUA
10	ELLEX MEDICAL PTY LTD	Australia
11	HAAG-STREIT AG	Elveția
12	HAAG-STREIT UK LIMITED	Marea Britanie
13	ISCON SURGICALS LIMITED	India
14	KANEHARA TRADING INC.	Japonia
15	KEELER LIMITED	Marea Britanie
16	LANG-STEREOTEST AG	Elveția
17	MADHU INSTRUMENTS PRIVATE LIMITED	India
18	MANI INC.	Japonia
19	MEDICEL AG	Elveția
20	MERIDIAN AG	Elveția
21	NATUS MEDICAL INCORPORATED DBA EXCEL-TECH LTD. (XLTEK)	Canada
22	OPTOVUE INC.	SUA
23	PLASMAPP CO., LTD	Coreea de Sud
24	RAY VISION INTERNATIONAL CORPORATION	China
25	RAYNER INTRAOCULAR LENSES LIMITED	Marea Britanie
26	REXXAM CO.LTD	Japonia
27	SHANGHAI MEDIWORKS PRECISION INSTRUMENTS CO. LTD.	China
28	SURGICAL SPECIALTIES MEXICO, S. DE R.L. DE C.V. ALSO TRADING AS SURGICAL SPECIALTIES CORPORATION	Mexic
29	SURGISTAR INC.	SUA
30	TEKIA INC.	SUA
31	TRACEY TECHNOLOGIES CORPORATION	SUA
32	TRANSAMERICAN TECHNOLOGIES INTERNATIONAL DBA TTI MEDICAL	SUA
33	UNICOS CO. LTD	Coreea de Sud
34	VISION ASSESSMENT CORPORATION	SUA
35	VOLK OPTICAL INC	SUA



Operatorul economic este distribuitor al producătorilor:

Nr crt	Nume producător	Țara
1	1 STQ GMBH	Germania
2	ADAPTICA SRL	Italia
3	AESULAP AG	Germania
4	ALBERT HEISS GMBH & CO.KG	Germania
5	ALBOMED GMBH	Germania
6	ARCADOPHTA	Franța
7	BON OPTIC VERTRIEBSGESELLSCHAFT MBH	Germania
8	CEFLA S.C.	Italia
9	CENTERVUE SPA	Italia
10	CSO SRL	Italia
11	D.O.R.C. DUTCH OPHTHALMIC RESEARCH CENTER (INTERNATIONAL) B.V.	Țările de Jos
12	HS DOMS GMBH	Germania
13	ICARE FINLAND OY	Finlanda
14	M.E.D.MEDICAL PRODUCTS GMBH	Germania
15	MABEL MAKINA MEDIKAL SANAYI VE TICARET A.S.	Turcia
16	MDJ SARL	Franța
17	MDT SP. Z O.O.	Polonia
18	MEDICONTUR MEDICAL ENGINEERING LTD	Ungaria
19	MELAG MEDIZINTECHNIK OHG	Germania
20	MERAN TIP URUNLERI TEKNOLOJI SAN. VE TIC. LTD. STI.	Turcia
21	MERIDIAN MEDICAL D.O.O.	Slovenia
22	NORLASE APS	Danemarca
23	QUANTEL MEDICAL	Franța
24	SERAG WIESSNER GMBH & CO.KG	Germania
25	SMI AG	Belgia
26	UFSK INTERNATIONAL OSYS GMBH	Germania

Prezentul document este valabil doar însoțit de avizul inițial.

VICEPREȘEDINTE  
Elena Valeria BRODEALĂ

