DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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,

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
Biometer Lenstar: **Biometer Lenstar LS 900 1009000** **Biometer Lenstar LS 900 APS 1009001** **Basic UDI-DI: 764013298LS9008S**	Class IIa	Biometer Lenstar LS 900	335325 MR2 Unique ID 170769818 NB 0297
Biometer Eyestar 900 1021400 **Basic UDI-DI: 764013298ES9006D**	Class IIa	Biometer Eyestar 900	335325 MR2 Unique ID 170769818 NB 0297
Perimeter Octopus 600 1803000 **Basic UDI-DI: 76401329806008C**	Class IIa	Perimeter Octopus 600	335325 MR2 Unique ID 170769818 NB 0297
Perimeter Octopus 900 1803000 **Basic UDI-DI: 76401329809008T**	Class IIa	Perimeter Octopus 900	335325 MR2 Unique ID 170769818 NB 0297
Applanation Tonometer AT 870 1420180 **Basic UDI-DI: 764013298AT8705Q**	Class I devices with a measuring function	Applanation Tonometer AT 870	335325 MR2 Unique ID 170769818 NB 0297
Applanation Tonometer (analog) AT 900: **Model BQ (1420152, 1420153, 1420156, 1420157)** **Model R (1420154)** **Model T (1420155)** **Basic UDI-DI: 764013298AT900_D7A**	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

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[1] 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

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

[1] As extended by the Regulation (EU) 2023/607 of the European Parliament and of the Council dated 15th 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[2]") 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[3] 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 [4].

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

[2] 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))

[3] 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

[4] 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 layed out in MDR, Article 10 (9) to 10 (13) [5].

[5] 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[6] 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[7] 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/Labelling:

   - *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[8] 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.

---

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.

[6] 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))

[7] 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))

[8] 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'?"

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).

The parties confirm that information provided in this Agreement[9] 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

DQS Medizinprodukte GmbH HRB 83350 August-Schanz-Str. 21 60433 Frankfurt am Main

Attached:

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

[9] 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)

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)[10]	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.
Biometer Lenstar LS 900 1009000	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Biometer Lenstar LS 900 APS 1009001	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Biometer Eyestar 900 1021400	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Octopus 900 1803000	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Octopus 600 1806000	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
AT 900, Model BQ 1420152 1420153 1420156 1420157	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**

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

AT 900 Model R **1420154**	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
AT 900 Model T **1420155**	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**

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: Name and legal form	Haag-Streit AG
Address: Street name, house No. ZIP-Code, City Country	Gartenstadtstrasse 10 3098 Koeniz Switzerland
Registration No. (SRN): *(according to Article 31)*	CH-MF-000020981
Contact person: Title, First name, Surname	Mrs Kerrie Mouncey
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)[11]	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.
Biometer Lenstar: **Biometer Lenstar LS 900 1009000** **Biometer Lenstar LS 900 APS 1009001** **Basic UDI-DI: 764013298LS9008S**	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Biometer Eyestar 900 1021400 **Basic UDI-DI: 764013298ES9006D**	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Perimeter Octopus 600 1803000 **Basic UDI-DI: 764013298O6008C**	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Perimeter Octopus 900 1803000 **Basic UDI-DI: 764013298O9008**T	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**
Applanation Tonometer AT 870 1420180	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**

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

Basic UDI-DI: 764013298AT8705Q		device under MDR			
Applanation Tonometer (analog) AT 900: **Model BQ (1420152, 1420153, 1420156, 1420157)** **Model R (1420154)** **Model T (1420155)** **Basic UDI-DI: 764013298AT900_D7A**	170769818 335325MR2	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31	**N/A**	**N/A**

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

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

Company: Name and legal form of the company	Haag-Streit AG
Address: Street, House No. ZIP Code, City Country	Gartenstadtstrasse 10 3098 Koeniz Switzerland
Contact Person: Title, First Name, Surname	Mrs Kerrie Mouncey
Phone / 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 –

1 Conformity Assessment

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

☐ **ISO 9001:2015 (DAkkS [1])**

☐ Initial Certification ☐ Re-Certification (Certificate-ID:)

Description of the scope [2]:

☐ **ISO 15378:2017 (DAkkS [1])**

☐ Initial Certification ☐ Re-Certification (Certificate-ID:)

Description of the scope [2]:

☐ **DIN EN ISO 15378:2018 (DAkkS [1])**

☐ Initial Certification ☐ Re-Certification (Certificate-ID:)

Description of the scope [2]:

☐ **ISO 13485:2016 (SCC [3])**

☐ Initial Certification ☐ Re-Certification (Certificate-ID:)

Description of the scope [2]:

☐ **(DIN EN) ISO 13485:2016 (DAkkS [1])**

☐ Initial Certification ☐ Re-Certification (Certificate-ID:)

Description of the scope [2]:

☐ **ISO 13485:2016 (TCP III [4])**

☐ Initial Certification ☐ Re-Certification (Certificate-ID:)

Description of the scope [2]:

[1] Certifications marked with „DAkkS" are carried out under accreditation of the German Accreditation Body (DAkkS).
[2] 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.
[3] Certifications marked with „SCC" are carried out under the accreditation of the Standards Council of Canada (SCC).
[4] 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 Certifcation ☐ Re-Certification [5] (Certificate-ID:)

For the following conformity assessment procedures [6]:

☐ **Annex IX Chapter I and III** [7]

☐ **Annex XI Part A** [7]

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

☐ **Transfer of Notified Body according to Article 58** [8]

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

☒ **Continuation of surveillance activities for MDD legacy devices according to Regulaion (EU) 2023/607** [9]

☐ **Transfer of surveillance activities for MDD legacy devices according to Regulaion (EU) 2023/607** [10]

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.

[5] 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".
[6] Separate application forms are required for each conformity assessment procedure.
[7] For supplementary conformity assessments of products, further information is required in the form Transfer Agreement Application Conformity Assessment Product (420_00).
[8] Further information is required in the supplementary form Transfer of Notified Body MDR (420_01).
[9] Further information is required in the supplementary form Application for Continuation of MDD Surveillance Activities (420_56).
[10] 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 [11] to the following conformity assessment procedures:

☐ **ISO 9001:2015 (DAkkS)** Certificate-ID:

Description and details of the change:

☐ **ISO 15378:2017 (DAkkS)** Certificate -ID:

Description and details of the change:

☐ **DIN EN ISO 15378:2018 (DAkkS)** Certificate -ID:

Description and details of the change:

☐ **ISO 13485:2016 (SCC)** Certificate -ID:

Description and details of the change:

☐ **(DIN EN) ISO 13485:2016 (DAkkS)** Certificate -ID:

Description and details of the change:

☐ **ISO 13485:2016 (TCP III)** Certificate -ID:

Description and details of the change:

☐ **Medical Device Single Audit Program (MDSAP)** Certificate -ID:

Description and details of the change:

☐ **Regulation (EU) 2017/745** [12] [13] Certificate -ID:

- ☐ **Annex IX Chapter I and III** [14]
- ☐ **Annex XI, Part A** [14]

Description and details of the change:

[11] A list of notifiable changes can be found in the General Business Conditions and the documents referenced therein.
[12] A separate application is required for each conformity assessment procedure.
[13] 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.
[14] 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	K.Mouncey
Place, date	Name, Signature	

Internal evaluation:

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

☐ Applicant	☐ CAP	☐ Basic dara	☐ Accr./Designation
☐ Signature	☐ Change	☐ List MD	☐ Ressources

Agreed on behalf of DQS MED:

Frankfurt a.M., 21.12.2023	i.A. N. Wimmer
Place, date	Name, Signature