Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 (MDR) regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MEDIO-HAUS MEDIZINPRODUKTE GmbH
Manufacturer address and contact details	Brunswiker Straße 50 24105 Kiel Germany
Single Registration Number (SRN) (if available)	DE-MF-000005313

Notified body name (if applicable)	DNV MEDCERT GmbH
Notified body number (if applicable)	0482
Directive Certificate number(s) to which this confirmation is made (if applicable)	2438DE414180612 2438GB414180612
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	23.03.2023
End date of extended validity/transition period	31.12.2028

Product group	Riboflavin
Risk class	IIa (MDD) / IIb (MDR)
EMDN-Code and description	Q020302: OPHTHALMOLOGY, LIQUID FLUIDS
Products	VibeX Rapid VibeX XTRA Trans-Epi Kit MedioCross (D, M, H, TE)

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above

- Directive Certificate(s) covering the listed device(s) were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

  Expired *after* 20 March 2023:

  Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

  A QMS in accordance with Article 10(9) MDR is in place.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

MEDIO-HAUS MEDIZINPRODUKTE GmbH

Kiel, 28.02.2024

[redacted]

Thomas Steffens PRRC

MEDIO-HAUS MEDIZINPRODUKTE GmbH
Brunswiker Straße 50
DE-24105 Kiel
medio-haus@gmx.de

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Model/Catalogue Number: MEDIOCROSS-D MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code[1]: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---
Model/Catalogue Number: MEDIOCROSS-M MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---

[1] As stated in Confirmation Letter by the Notified Body

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Model/Catalogue Number: MEDIOCROSS-H MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---
Model/Catalogue Number: MEDIOCROSS-TE MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---
Model/Catalogue Number: VIBEX-RAPID MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Model/Catalogue Number: VIBEX-XTRA MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---
Model/Catalogue Number: TRANS-EPI MDN Code: Non-active non-implantable ophthalmologic devices EMDN Code: Ophthalmology, Liquid Fluids MDD Certificate Scope: Riboflavin solutions for Corneal Collagen Cross-Linking	2438DE414180612 2438GB414180612	23.03.2023	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31.12.2028	---