Manufacturer's Declaration

in relation to 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, 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	Hager & Werken GmbH & Co. KG
Manufacturer address and contact details	Ackerstr. 1, 47269 Duisburg, Germany
Single Registration Number (SRN) (if available)	DE-MF-000004938

Authorised Representative name (if applicable)	-
Authorised Representative address and contact details	-
Single Registration Number (SRN) (if available)	-

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH
Notified body number (if applicable)	0197
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 1011605-1 DD 1011605-1
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) 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 Certificates** as listed above or in the attached schedule

  Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

  The Directive Certificates expired *after* 20 March 2023.

  Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Upclassified devices**

  Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement is 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.

- **Devices as listed in the attached schedule**

  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices 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:

Full Company Name	Hager & Werken GmbH & Co. KG
Location & Date	Duisburg, 08.07.2024
Signature, Print Name, Title	, Christian Nolden, QMB
Contact Details (at least email)	c.nolden@hagerwerken.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)	**Basic UDI-DI**	**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)
mirafluor-gel	40996370063004P	n/a	n/a	n/a	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a
Lunos Fluoridgel	40996370063004P	n/a	n/a	n/a	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a
Mara Expert Protector Fluorid Gelee	40996370063104S	n/a	n/a	n/a	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a
Xylimed	40996370065004Z	n/a	n/a	n/a	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a
Xylimed Kids	40996370065004Z	n/a	n/a	n/a	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a
SOS-Zahnbox	40996370064004U	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	SOS Zahnbox /DENTOSAFE
Dentosafe	40996370064004U	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	SOS Zahnbox /DENTOSAFE

Super Splint	40996370009004B	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Super Splint (De Luxe)
Prophy Brush (Zylinder)	40996370067505S	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Bürsten
Prophy Brush (Kelch - weiß + gelb)	40996370067505S	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Bürsten
Prophy Angles (regular)	40996370067005B	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Angles
Prophy Angles (soft)	40996370067005B	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Angles
Prophy Cups (schraubbar - blau + grün)	40996370067005B	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Cup
Prophy Cups (snap-on - blau + grün + gelb)	40996370067005B	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Cup
Prophy Cups (WST - blau + grün)	40996370067005B	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Prophy Cup
LaserHF Bare Fiber (AS 200/240 + AS 320/385)	40996370015003W	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Laser Bare Fiber
hf1 Surg bipolar	40996370012003F	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a

hf Surg	40996370012003F	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	n/a
Miraject Endo Luer (0,3 x 40 mm + 0,5 x 40 mm)	40996370028004L	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (stumpf)
Miraject Endotec Luer (0,3 x 25 mm + 0,4 x 25 mm + 0,5 x 25 mm + 0,6 x 25 mm + 0,8 x 25 mm)	40996370028004L	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (stumpf)
Miraject Endotec Duo (0,3 x 25 mm + 0,4 x 25 mm + 0,5 x 25 mm + 0,6 x 25 mm)	40996370028004L	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (stumpf)
Miraject Carpule (17/23 + 17/42 + 30/23 + 30/42 + 40/23 + 40/10)	40996370027004F	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (spitz)
Miraject Luer (17/23 + 17/42 + 30/23 + 30/42)	40996370027004F	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (spitz)
Miraject P	40996370028004L	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (stumpf)
Miraject P Super	40996370028004L	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (stumpf)

Miraject PL Super	40996370028004L	HD 60149483 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Miraject (stumpf)
Variator-Kit	40996370054004M	DD 60149479 0001	26.05.2024	TÜV Rheinland LGA Products GmbH (0197)	TÜV Rheinland LGA Products GmbH (0197)	31.12.2028	Variator Dental Kit