Wir, die Firma

We, the company,

HÄLSA Pharma GmbH
Maria-Goeppert-Strasse 5
D-23562 Lübeck

Erklären in eigener Verantwortung, dass das Produkt:

Hereby declare in our own responsibility that the device:

tetesept Meerwasser Nasen Spray Care
(s. TD 7.1)

tetesept Meerwasser Nasen Spray Care
(refer to TD 7.1)

mit den Anforderungen der folgenden Richtlinien übereinstimmt:
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte.

is/are in compliance with the following directive:
Council Directive 93/42/EEC of 14th June 1993 concerning medical devices

Konformitätsbewertungsverfahren

nach Anhang *VII*
der oben genannten Richtlinie

Conformity Assessment Procedure

according to annex *VII*
of the Council Directive named above

Klassifizierung

nach Anhang IX der
oben genannten Richtlinie
Klasse *I*

Classification

according to annex IX of the
Council Directive named above
Class *I*

Benannte Stelle

nicht relevant (Medizinprodukt der Klasse I)

Notified Body

not relevant (medical device of class I)

Referenznormen

Anwendbare Normen sind Bestandteil der Technischen Dokumentation und können auf Wunsch eingesehen werden

Reference Standards

Applicable standards are part of the technical documentation and can be looked up upon request

Gültigkeit

Diese Konformitätserklärung ist gültig bis zum 27.05.2024.

Validity

This declaration of conformity is valid until 2024-05-27.

Lübeck, 2021-01-19
(Datum /date)

Timo Bohnhoff
(Geschäftsleitung / Management)

Hälsa Pharma GmbH · Maria-Goeppert-Str. 5 · 23562 Lübeck · Germany

Lübeck, 19.04.2024

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 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- 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	**HÄLSA Pharma GmbH**
Manufacturer address and contact details	Maria-Goeppert-Str. 5 23562 Lübeck Germany vigilance.haelsa@diapharm.de
Single Registration Number (SRN) (if available)	**DE-MF-000007407**

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- 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 or in the attached schedule

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

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have 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.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☐ **Expired/expires *after* 20 March 2023**:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have 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 substitutes 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.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made and submitted by us to the Notified Body DNV MEDCERT GmbH on **29 December 2023** for the device(s) listed in the attached schedule or its/their substitute(s) and **signed written agreement(s) is already**

in place in accordance with Section 4.3, second subparagraph of Annex VII MDR. **Confirmation letter of DNV MEDCERT GmbH is attached.**

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have 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 substitutes 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.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

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

  ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

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

  - The device(s) continue to comply with the AIMDD or 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:

Full Company Name	HÄLSA Pharma GmbH
Location & Date	Lübeck, 19.04.2024
Signature, Print Name, Title	Dr. Bernhard Weber, PRRC

Hälsa Pharma GmbH · Maria-Goeppert-Str. 5 · 23562 Lübeck · Germany

Schedule of Devices

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

Identification of the device(s)[3] (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)
tetesept Meerwassernasenspray	Not applicable	Not applicable	Not applicable	DNV Medcert GmbH (0482)	2028-12-31	Not applicable
tetesept Meerwassernasenspray Care	Not applicable	Not applicable	Not applicable	DNV Medcert GmbH (0482)	2028-12-31	Not applicable
tetesept Rhinolind Akut Abschwellendes Nasenspray	Not applicable	Not applicable	Not applicable	DNV Medcert GmbH (0482)	2028-12-31	Not applicable
tetesept Schnupfen Spray	Not applicable	Not applicable	Not applicable	DNV Medcert GmbH (0482)	2028-12-31	Not applicable

Note:
The above mentioned medical device is covered by MDN Code 1213: **Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** in the attached confirmation letter. Confidential information for other devices is blackened.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)