| Anlage 1 zur VA QM 7.1.3-00 | **TD 7.2 Declaration of Conformity Konformitätserklärung** | | Diapharm Hälsa Pharma GmbH |
|---|---|---|---|
| Dokument-Nr.: FB-71201 | FB-Version: 10.0 | Page 1 of 1 | |

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 Hals und Rachen Spray

(s. TD 7.1)

tetesept Hals und Rachen Spray

(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 *V in Verbindung mit Anhang VII* der oben genannten Richtlinie

**Conformity Assessment Procedure**

according to annex *V combined with annex VII* of the Council Directive named above

**Klassifizierung**

nach Anhang IX der oben genannten Richtlinie
Klasse *IIa*

**Classification**

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

**Benannte Stelle**

MedCert GmbH
Pilatuspool 2
D-20355 Hamburg
Kennnummer: 0482

**Notified Body**

MedCert GmbH
Pilatuspool 2
D-20355 Hamburg
Identification number: 0482

**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 basierend auf der EG-Konformitätsbescheinigung, 3558DE414200519

**Validity**

This declaration of conformity is valid based on the EC Certificate of Conformity, 3558GB414200519.

Lübeck, 22. MAI 2020
(Datum /date)

T. Bohnhoff
Timo Bohnhoff
(Geschäftsleitung / Management)

MED CERT®

Certification. Medical Only.

# EG-Konformitätsbescheinigung

**Die Benannte Stelle**

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**
**Pilatuspool 2 – 20355 Hamburg – Deutschland**

bescheinigt hiermit, dass das Unternehmen

**HÄLSA Pharma GmbH**
**Maria-Goeppert-Straße 5**
**23562 Lübeck**
**Deutschland**

für die Produkte / Produktkategorien gemäß Anlage ein Qualitätssicherungssystem eingeführt hat, anwendet und aufrechterhält.

Durch ein Audit wurde der Nachweis erbracht, dass dieses Qualitätssicherungssystem die unten genannten Anforderungen der Richtlinie 93/42/EWG des Rates erfüllt:

## Anhang V

Dies wird von MEDCERT überwacht.

| | |
|---|---|
| **Gültig ab:** | **2020-05-19** |
| **Gültig bis:** | **2024-05-27** |

| | |
|---|---|
| Berichts-Nr.: | 3558FS16F |
| Verfahrens-Nr.: | QS – 3558 |
| Bescheinigungs-Nr.: | 3558DE414200519 |

Hamburg, 2020-05-19

MEDCERT-Zertifizierungsstelle
(Dr. Andreas Schich)

Die Bescheinigung ist nur gültig, wenn sie mit allen Seiten vollständig vorliegt. Bitte wenden Sie sich an info@medcert.de, um die Gültigkeit der Bescheinigung zu überprüfen.

MEDCERT-Kennnummer: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MED CERT®

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## Anlage der EG-Konformitätsbescheinigung

Verfahrens-Nr.: QS – 3558
Bescheinigungs-Nr.: 3558DE414200519

### Liste der Produkte / Produktkategorien im Geltungsbereich der Bescheinigung

- **Isotonische NaCl-Lösungen**
- **Sterile NaCl-Lösungen**
- **Physikalisch wirkende Produkte zur Behandlung von Magen- und Darmbeschwerden**
- **Physikalisch wirkende Produkte zur topischen Anwendung**
- **Produkte zur Behandlung von trockenen Augen**
- **Produkte zur Behandlung von Vaginalbeschwerden**
- **Produkte zur Linderung von Hämorrhoidalbeschwerden**
- **Produkte zur Behandlung von Halsschmerzen, trockenem Husten und Heiserkeit**
- **Physikalisch wirkende Produkte zur Anwendung auf der Schleimhaut**

– Ende der Liste –

Diese Anlage ist integraler Bestandteil der oben angegebenen Bescheinigung. Die Bescheinigung ist nur gültig, wenn sie mit allen Seiten vollständig vorliegt. Bitte wenden Sie sich an info@medcert.de, um die Gültigkeit der Bescheinigung zu überprüfen.

MEDCERT-Kennnummer: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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<br>23562 Lübeck<br>Germany<br>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)<br>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 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.**

☐ 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 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 Hals und Hustenreiz Lutschtabletten & tetesept Angionosan Junior Erdbeere Zuckerfrei Halstabletten | 3558GB414200519 | 2024-05-27 | DNV Medcert GmbH (0482) | DNV Medcert GmbH (0482) | 2028-12-31 | Not applicable |
| tetesept Hals und Rachen Spray | 3558GB414200519 | 2024-05-27 | DNV Medcert GmbH (0482) | 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)

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

**Date**: 2024-04-16

**Our reference**: QS-3558

**Notified Body Confirmation Letter**
**Certification No: 3558GB454240416**

**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**

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], 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.

HÄLSA Pharma GmbH
Maria-Goeppert-Straße 5
23562 Lübeck
Germany
SRN[2]: DE-MF-000007407

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB 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 the NB 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 20 March 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:

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.

[2] Single registration number (SRN) according to Article 31 (2) of MDR.

- 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 devices, 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)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

**Appendix**

**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 or Basic UDI-DI (under MDR 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 |
|---|---|---|---|
| **Non-active non-implantable devices for wound and skin care** | Class IIa | N/A | Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482 |
| **Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** | Class IIa | N/A | Certificate 3558DE410210521A NB 0482 Certificate 3558GB410210521A NB 0482 Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482 Certificate 3558DE415200519 NB 0482 Certificate 3558GB415200519 NB 0482 |
| **Orally administered devices for the therapy of gastro-intestinal disorders** | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482 |
| **Orally administered devices for the therapy of gastro-intestinal disorders** | Class IIb excluding Class IIb implantable non-WET | [redacted] | Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482 |
| **Nasopharyngeal devices - other** | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 3558DE410210521A NB 0482 Certificate 3558GB410210521A NB 0482 |
| **Topical anorectal administered gastro-intestinal system devices** | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482 |
| **Ophthalmology, liquid fluids** | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 3558DE414200519 NV 0482 Certificate 3558GB414200519 NB 0482 |

| | | | |
|---|---|---|---|
| **Inhalation therapy humidification liquids** | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 3558DE414200519 NB 0482 Cerfificate 3558GB414200519 NB 0482 |
| **Vaginal devices in the form of solutions/creams/ ova/tablets** | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 3558DE414200519 NB 0482 Cerfificate 3558GB414200519 NB 0482 |
| **Vaginal devices in the form of solutions/creams/ ova/tablets** | Class IIb excluding Class IIb implantable non-WET | [redacted] | Certificate 3558DE414200519 NB 0482 Cerfificate 3558GB414200519 NB 0482 |
| **42517781MD315CS** | Class III | N/A | Certificate 3558DE414200519 NB 0482 Cerfificate 3558GB414200519 NB 0482 |
| **42517781MD339D8** | Class III | N/A | Certificate 3558DE414200519 NB 0482 Cerfificate 3558GB414200519 NB 0482 |
| **42517781MD319D2** | Class III | N/A | Certificate 13980DE411200525 NB 0482 Cerfificate 13980GB411200525 NB 0482 |
| **42517781MD340CR** | Class III | N/A | Certificate 3558DE414200519 NB 0482 Cerfificate 3558GB414200519 NB 0482 |
| **Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** | Class IIa | N/A | N/A |
| **Non-active non-implantable devices for wound and skin care** | Class IIa | N/A | N/A |

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

| Device name or Basic UDI-DI (under MDR 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 |
|---|---|---|---|
| **None** | None | None | None |

**Confirmation Letter Revision History:**

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024-04-16 | 3558GB454240416 | Initial issue |