

Anlage 1 zur VA-71200	TD 7.2 Declaration of Conformity Konformitätserklärung		
Dokument-Nr.: FB-71201	FB-Version: 11.0	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 Hustenreiz Lutschtablette &
tetesept Anginosan Junior Erdbeere Zuckerfrei
Halstabletten

tetesept Hals und Hustenreiz Lutschtablette &
tetesept Anginosan Junior Erdbeere Zuckerfrei
Halstabletten

(s. TD 7.1)

(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

Conformity Assessment Procedure

nach Anhang V in Verbindung mit Anhang VII
der oben genannten Richtlinie

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

Klassifizierung

Classification

nach Anhang IX der
oben genannten Richtlinie
Klasse IIa

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

Benannte Stelle

Notified Body

MedCert GmbH
Pilatuspool 2
D-20355 Hamburg
Kennnummer: 0482

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

Referenznormen

Reference Standards

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

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

Gültigkeit

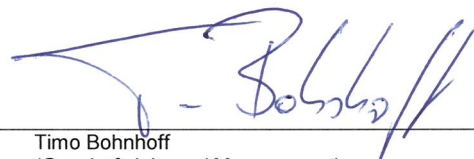
Validity

Diese Konformitätserklärung ist gültig basierend auf
der EG-Konformitätsbescheinigung,
3558DE414200519

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

Lübeck, 2020-08-21

(Datum /date)



Timo Bohnhoff
(Geschäftsleitung / Management)

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

Form F10010005 DE / Rev. 11 / 2019.11.14



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

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 vaginalen Beschwerden**
- **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



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www.zlg.de
ZLG-BS-237.10.15

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-00007407

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)	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	<input checked="" type="checkbox"/> 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 intend 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 intend 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 Nando¹, 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
SRN²: 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.



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- 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



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 gastrointestinal 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 gastrointestinal 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 gastrointestinal 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 Certificate 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 Certificate 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 Certificate 3558GB414200519 NB 0482
42517781MD315CS	Class III	N/A	Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482
42517781MD339D8	Class III	N/A	Certificate 3558DE414200519 NB 0482 Certificate 3558GB414200519 NB 0482
42517781MD319D2	Class III	N/A	Certificate 13980DE411200525 NB 0482 Certificate 13980GB411200525 NB 0482
42517781MD340CR	Class III	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	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 NOT 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