# EU Quality Management Certificate

This is to certify that the company

## Engelhard Arzneimittel GmbH & Co. KG

Herzbergstraße 3
61138 Niederdorfelden
Germany

SRN: DE-MF-000025566

has established, implemented and maintains a Quality Management System in accordance with

## Annex IX, Chapter I and III of the Regulation (EU) 2017/745

**Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

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| Certificate registration no. | 321520 MDR2017Q |
| Certificate ID | 1000207095 |
| Effective date | 2024-11-28 |
| Expiry date | 2028-09-26 |
| Frankfurt am Main, | 2024-11-28 |

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

**DQS Medizinprodukte GmbH**

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.**
**The validity of the certification can only be verified by the QR-code.**



420.90 Version 7.0

# Annex to EU Quality Management Certificate
# SRN of Manufacturer: DE-MF-000025566
# Certificate ID: 1000207095

**Device categories and variants covered by this certificate:**

| | |
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| Device category: | **MDN 1213 - Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** |
| Product name: | Nisita Nasal Ointment |
| Risk classification: | IIa |
| Basic-UDI-DI: | 4104480Nisita_OintmentXN |
| Intended purpose: | Protection and moistening of dry nasal mucous membrane and support to its cleaning function |

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| Device category: | **MDN 1213 - Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** |
| Product name: | Isla lozenges |
| Risk classification: | IIa |
| Basic-UDI-DI: | 4104480islaCA |
| Intended purpose: | Moisturizes and protects dry mucous membranes in the throat and pharynx. For the relief of cold, throat and voice complaints. |

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| Device category: | **MDN 1213 - Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** |
| Product name: | isla med lozenges |
| Risk classification: | IIa |
| Basic-UDI-DI: | 4104480isla_medTG |
| Intended purpose: | Moisturizes and protects the mucous membrane in the throat and pharynx. Relief from cough irritation, hoarseness and throat discomfort. |

**Examinations and tests performed:**
321520_A208105MED_01 vom 11.01.2022
321520_A208105MED_03 vom 29.08.2023
321520_A208105MED_04 isla lozenges dated 2024-11-24
321520_A208105MED_05 isla med lozenges dated 2024-11-24

**Further conditions for or limitations to the validity of the certificate:**
n/a

**Reference to previous certificates:**

| Revision | Date of Issue | Certificate-ID | Description of change |
|---|---|---|---|
| 01 | 2023-09-27 | 170776234 | Change of Certificate Template |
| 02 | 2024-08-04 | 1000169582 | Addition of “Isla lozenges” and “isla med lozenges” |