

DECLARATION OF QUALITY FOR PAPILLA SEALANT PRODUCT

Non-Medicinal Product – Not Classified as a Pharmaceutical

The undersigned **Bruno Cantarelli, Tax Code CNTBRN55T13B034E**,
as **Doctor in Biotechnology** and **legal representative** of the company **CNT LAB S.r.l.**,
with registered and operational headquarters in **43036 Fidenza (PR), Italy**,
Tax Code and VAT Number **02674260340**, Tel. **+39 3772676345**,

Aware of the criminal penalties provided for under Article 76 of Presidential Decree No. 445/2000 in
cases of false statements and misleading declarations,

HEREBY DECLARES under his own responsibility that:

1. Production and Compliance with Standards

The **Papilla Sealant** is **manufactured and packaged** in compliance with **applicable regulations for medical devices** at a **certified production site**. The company operates a **modern and technologically advanced production facility**, adhering to the **strictest environmental and safety regulations** currently in force in Europe.

The **in-house chemical laboratory** is dedicated to **research, development, and quality control**, with a particular focus on **innovation and environmental sustainability**.

2. Regulatory Status of Papilla Sealant

The **Papilla Sealant** is **not classified or registered as a medical device or medicinal product**, as it does not fall under these categories. It is an **organic sealing paste** designed **exclusively for protecting the teats of dairy cows**.

Consequently, the product **does not require registration as a medicinal or phytotherapeutic product**, as its **function is purely mechanical and protective**, with no therapeutic purpose.

3. Quality Control and Raw Material Safety

The **quality control** of the raw materials used has been **conducted directly by our laboratory**, ensuring:

- ☑ **Exclusive use of non-toxic and safe materials**, both for animals and operators.
- ☑ **Strict supplier selection**, verified by our **chemists and biologists** to guarantee **high safety and reliability standards**.



4. Exclusion from the Status of Veterinary Medicinal Product Subject to Prescription

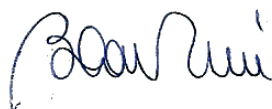
In compliance with **Regulation (EU) 2019/6, Article 34**, Papilla Sealant is not classified as a veterinary medicinal product subject to prescription, as it:

- **Does not contain narcotic or psychotropic substances.**
- **Is not intended for food-producing animals for therapeutic purposes.**
- **Is not an antimicrobial.**
- **Is not intended for treatments requiring a prior precise diagnosis or that may interfere with further diagnostic or therapeutic procedures.**
- **Is not used for animal euthanasia.**
- **Does not contain active substances authorized within the EU for less than five years.**
- **Is not an immunological medicinal product.**
- **Does not contain substances with hormonal, thyrostatic, or beta-agonist activity.**

Additionally, any modification of status is **excluded** for the **categories specified in points a), c), e), and h)** of the aforementioned Regulation.

Date: July 27, 2023

Company Stamp and Signature of the Legal Representative



DECLARATION OF SAFETY FOR PAPILLA SEALANT PRODUCT

1. Compliance with Product Commercialization and Safety Regulations

The **Papilla Sealant** has been manufactured in compliance with current regulations regarding **prohibitions on commercialization, information, and product safety**, particularly:

- **Article 11 - Prohibitions on Commercialization**
 - a. It is prohibited to market any product or product packaging within the national territory that does not clearly display, in visible and legible form, the indications required by Articles **6, 7, and 9**.
 - b. **Article 6** – Minimum content of information
 - c. **Article 7** – Indication methods
 - d. **Article 9** – Indications in the Italian language
- **Product Safety and Quality**
 - a. **Article 103** – Definitions
 - b. **Article 104** – Obligations of the producer and distributor

2. Product Safety and Verification

🐾 **Papilla Sealant** has been **verified, tested, and examined over time** with the support of numerous veterinarians, who have confirmed **its safety in use**.

🐾 The product is **made exclusively from safe and carefully selected materials** to ensure **maximum protection**.

🐾 The **syringe used** is **inspected and verified** by the **certified third-party filler**.

🐾 The **sealing paste** undergoes **strict quality controls** by our internal regulatory department.

3. Composition and Safety of Ingredients

All components of **Papilla Sealant** are **carefully selected** by our **chemists and biologists**, ensuring an **effective and safe product** for both animals and operators.

- **Organic Beeswax** – A natural substance produced by bees of the *Apis* genus, commonly used in the production of **cosmetics and pharmaceutical products**, including **bone wax**.
- **Propylene Glycol** – A **humectant agent** that helps maintain the product's proper hydration.
- **Vegetable Glycerol** – A **viscous substance** that improves the **product's adhesion to the teat sphincter**, enhancing protection.
- **Distilled Water** – Used as a **solvent** to ensure the product's homogeneity.



- **Distilled Water with Silver Ions (0.008%)** – Used to **preserve the product**. The **silver ions in clusters** (not nanoparticles) ensure **optimal microbiological stability**.
- **Glycolic Cucumber Extract** – A **mineralizing, purifying, and refreshing substance** for the skin, promoting **animal well-being**.
- **Polyvinylpyrrolidone (PVP)** – A material with **antistatic and stabilizing properties**, which, in combination with **vegetable glycerol**, creates a **strongly adherent paste** for the teat sphincter.
- **Sepigel** – An essential ingredient for **binding all components**, ensuring the **optimal consistency** for the intended use.

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DECLARATION OF EFFICACY FOR PAPILLA SEALANT PRODUCT

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Aware of the criminal penalties provided for under Article 76 of Presidential Decree No. 445/2000 in cases of false statements and misleading declarations,

HEREBY DECLARES under his own responsibility that:

1. Function and Mechanism of Action

The **Papilla Sealant** has been **tested for the mechanical sealing of the teat** in dairy cows to **reduce the risk of pathogen entry** into the **mammary cistern**. Its effect is purely **mechanical and non-pharmacological**.

2. Efficacy Tests and Results

🐄 Tests conducted on **dry cows** in **various farms** have demonstrated that **Papilla provides effective sealing**, reducing the risk of **bacterial contamination** during the dry period.

3. Safety for Animals, Operators, and the Environment

🐄 The **Papilla Sealant does not pose any direct or indirect risk** to:

- **The animals** to which it is applied.
- **The operators** who administer it.
- **The environment** where it is used.

🐄 There is **no risk to public health** concerning **sealant residues in the milk** of treated animals, as the product is formulated with **safe ingredients compatible with food production**.

Date: July 27, 2023

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