

Office 4, 21 Knightsbridge - SW1X 7LY London UK Company n.07961030 Capital Share: 9.080.193,00 € paid General Manager: Bruno Cantarelli

Scientific Director: Dr. Arturo Sommariva

SALVALAT Lavanda Funzionale of the Animal Health Line is an intramammary solution of bio-inorganic origin specifically designed for the effective removal of bacterial biofilm formed in the milk ducts and udder cistern of dairy cows. The product has a localized effect on the mucosal surfaces of the udder without causing systemic effects. It is not an antibiotic, does not penetrate body tissues, and does not distribute across the animal's systems.

### SOMATIC CELLS IN MILK – A RELEVANT VETERINARY ISSUE

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### SOMATIC CELLS: WHAT ARE THEY? HOW MANY?

In a healthy quarter of the udder, the somatic cell count is less than 200,000.

Typically, less than 100,000:

0-7% epithelial cells

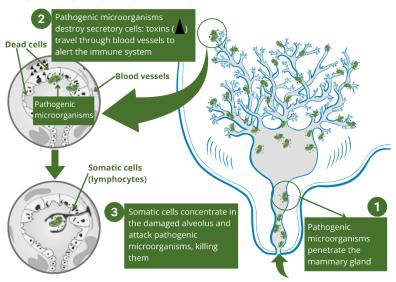
- 60% macrophages
- 30% B and T lymphocytes
- 10% neutrophils (PMNs)

THIS IS THE IMMUNE RESPONSE TO THE ENTRY OF PATHOGENS (BACTERIA, FUNGI, ALGAE) INTO UDDER TISSUES, CAUSING INFLAMMATION.

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### **MECHANISM OF FORMATION**



- 1. Pathogenic microorganisms penetrate the udder (as shown in the image).
- 2. **Pathogenic microorganisms destroy secretory cells:** toxins activate the body's defense systems through blood vessels (as shown in the image).
- 3. Somatic cells concentrate in the damaged alveoli and attack pathogens, destroying them (as shown in the image).

### Mechanism of the Inflammatory Response in the Cow's Udder

Stage	Description	Actions and Reactions
1. Pathogen Penetration	Pathogenic microorganisms (bacteria, fungi, algae) enter the milk ducts and alveoli of the udder.	Pathogen multiplication triggers the activation of the immune system.
2. Cell Destruction and Activation of the System	Pathogens release toxins that destroy the secretory cells of the mammary gland. Toxins activate immune cells through blood vessels.	- Secretory cells die. - Immune cells are directed to the affected area.
3. Immune Response: Action of Somatic Cells	Somatic cells (macrophages, lymphocytes, neutrophils) concentrate in the affected alveoli.	<ul><li>Somatic cells attack pathogens.</li><li>Pathogens are destroyed, and inflammation is reduced.</li></ul>

# WHAT CAUSES AN INCREASE IN SOMATIC CELLS? HOW MUCH DOES MASTITIS COST THE FARM?

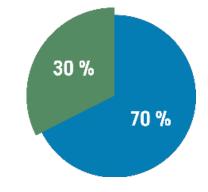
### In the image:

### Blue Color - PRODUCTION LOSSES

- 200,000 somatic cells = 0% loss
- 500,000 somatic cells = 6% loss
- 1,000,000 somatic cells = 18% loss
- 1,500,000 somatic cells = 29% loss

### Green Color - OTHER LOSSES

- Reduction in milk price
- Costs of therapy
- Discarded milk
- Increased expenses for herd renewal





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	EU DIRECTIVE	
(Regulation 852/2004) NEW HYGIENE REGIME FOR FOOD PRODUCTS	(Regulation 178/2002)	(Regulation 854/2004) OFFICIAL CONTROL OF PRODUCTS OF ANIMAL ORIGIN INTENDED FOR HUMAN CONSUMPTION
(Regulation 853/2004) SPECIFIC HYGIENE RULES APPLICABLE TO FOODSTUFFS OF ANIMAL ORIGIN	(Regulation 882/2004) OFFICIAL CONTROL OF ANIMAL-BASED PRODUCTS INTENDED FOR HUMAN CONSUMPTION	(Regulation 853/2004) SPECIFIC HYGIENE RULES APPLICABLE TO FOODSTUFFS OF ANIMAL ORIGIN
		(Regulation 2002/99 CE)  VETERINARY POLICIES REGULATING THE  PRODUCTION AND DISTRIBUTION OF  ANIMAL-BASED PRODUCTS INTENDED  FOR HUMAN CONSUMPTION

### PARAMETERS (SMOOTHING MOVING GEOMETRIC AVERAGE)

### **Table: Raw Milk Control Parameters**

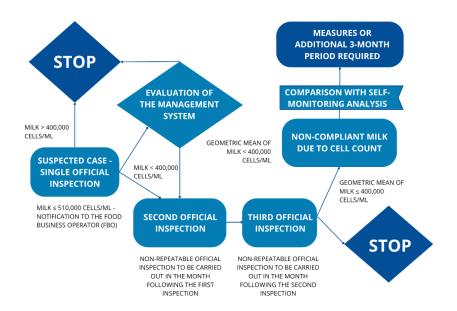
Product Type	Criterion	Limit	Calculation Method	Control Frequency
Raw cow's milk	Microbial content at 30°C (per ml)	≤ 100.000	Smoothing moving geometric average calculated over a 60-day period	At least one sample every 15 days
	Somatic cell content (per ml)	≤ 400.000	Smoothing moving geometric average calculated over a 90-day period	At least one sample every 30 days
Raw milk from other animal species	Microbial content at 30°C (per ml)	≤ 1.500.000	Smoothing moving geometric average calculated over a 60-day period	At least one sample every 15 days
Raw milk from other animal species intended for the production of heat-treated products	Microbial content at 30°C (per ml)	≤ 500.000	Smoothing moving geometric average calculated over a 60-day period	At least one sample every 15 days

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### MONITORING SYSTEM

### DIAGRAM FOR CONDUCTING OFFICIAL ANALYTICAL CONTROLS



The diagram represents the system for monitoring somatic cell count (SCC) in milk, detailing the steps from the initial analysis to the implementation of corrective actions or the cessation of inspections.

The process for monitoring milk for somatic cell content includes the following stages:

#### Initial Check:

- If the milk contains ≤ 400,000 cells/mL, the inspection process is terminated, and the milk is deemed compliant with standards (STOP).
- If the somatic cell count exceeds 400,000 cells/mL, there is suspicion of an issue, and the first official inspection is conducted.

### 2. Second Official Inspection:

- If the second test confirms an SCC exceeding 400,000 cells/mL, a third official inspection is
- If the SCC exceeds 510,000 cells/mL, information is reported to the competent authorities (OSA), as this indicates a serious violation.

### 3. Third Official Inspection:

- If the geometric mean SCC from the three tests exceeds 400,000 cells/mL, the milk is classified as non-compliant.

### Follow-Up Actions for Non-Compliance:

- The results are compared with self-monitoring data from the farm.
- If non-compliance is confirmed, measures are taken (e.g., treating affected animals, improving housing or feeding conditions), or an additional 3-month observation period is imposed.

### 5. Conclusion of Inspections:

- If, after all measures, the geometric mean SCC is ≤ 400,000 cells/mL, the milk is deemed compliant, and the inspection is concluded (STOP).
- This process ensures milk quality control, prevents the spread of diseases within the herd, and minimizes health risks for consumers.



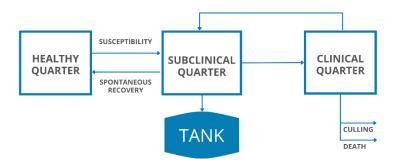
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### DYNAMICS OF SUBCLINICAL MASTITIS DEVELOPMENT

### (High Somatic Cell Count)

Subclinical mastitis with elevated SCC may result in either spontaneous remission or require antibiotic treatment.



The diagram illustrates the dynamics of changes in the condition of udder quarters:

- A healthy quarter may become subclinical due to susceptibility or return to a normal state through spontaneous remission.
- A **subclinical quarter** can progress to a clinical state, be directed to the bulk tank, or revert to a healthy state.
- A **clinical quarter** is either directed to the bulk tank, leads to culling, or results in the death of the animal.



# NATIONAL PLAN FOR COMBATING ANTIBIOTIC RESISTANCE PUBLISHED

For every new natural antimicrobial substance, a corresponding resistance mechanism exists in nature. The introduction of antibiotics in both human and veterinary medicine has created additional selective pressure.

The first National Plan for Combating Antibiotic Resistance (PNCAR 2017–2020), approved by the STATE-REGION conference, was published on the website of the Ministry of Health.

The National Plan for Combating Antimicrobial Resistance (PNCAR) 2017–2020 was approved on November 2, 2017, through an agreement between the Government, the Regions, and the autonomous provinces of Trento and Bolzano. The plan aims to address antibiotic resistance, a significant issue in Italy.

 $(https://www.salute.gov.it/portale/documentazione/p6\_2\_2\_1.jsp?id=2660\&utm\_source=chatgpt.com).$ 

You can read the full text of the plan on the official website of the Italian Ministry of Health at the following link:

https://www.salute.gov.it/imgs/C 17 pubblicazioni 2660 allegato.pdf?utm source=chatgpt.com

### ANTIBIOTIC CATEGORIZATION: INCLUSION OF CIAS

CIAs (Critically Important Antibiotics) are a category of antibiotics identified by the World Health Organization (WHO) as critically important for treating human infections. The inclusion of such antibiotics in monitoring and usage plans is aimed at reducing their application in veterinary medicine to minimize the risk of developing antibiotic resistance.

Antibiotic categorization is based on the following criteria:

- The importance of the antibiotic for treating infections in humans.
- The risk of resistance development associated with its use in veterinary medicine.

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The availability of alternative treatments for animals.

Table: Classification of antibiotics and their usage.

Tadie: Classification of anti	biolics and tricir asage.	
Category	Description	Note
EMA	Classification of antibiotics for use in animals to promote prudent and responsible application.	Prudent use reduces the risk of developing bacterial resistance.
One Health	Antibiotic resistance can spread between humans, animals, and the environment.	A multidisciplinary approach is required to control the spread of resistance.
AMEG Expert Group	Classification of antibiotics based on their impact on public health and the need for use in animals.	Considers the risk of resistance and the importance of the drug in veterinary medicine.
Special Attention	Antibiotics used in both humans and animals, as well as last-resort drugs for severe infections.	Misuse could lead to the loss of their effectiveness in human medicine.





The images provide information about the National Pharmacovigilance Information System and electronic veterinary prescriptions.

### First Image:

#### Key functions of the system:

- Electronic prescription.
- Electronic treatment registry.
- Complex issues related to withdrawal periods.
- Computerized Model 4.

### Second Image:

### Access instructions:

- Use the Google Chrome browser.
- Enter "VETINFO" in the search bar.
- Click on the "RICETTA ELETTRONICA" button.

### ANTIBIOTIC USE IN CATTLE

**Legislation,** in addition to introducing antibiotic categorization for cattle, prohibits any form of preventive antibiotic use. One of the most common preventive practices is antibiotic therapy during the dry-off period.

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### DRY COW THERAPY

"Blanket" antibiotic therapy when transitioning cows to the dry period is a widely used practice in dairy farming to reduce the prevalence and frequency of intramammary infections (IMI).

This therapy is part of the Recommended Mastitis Control Program (NMC Factsheet – Dry Cow Therapy).

Mastitis is the most costly disease in dairy farming. Approximately 70–80% of economic losses are associated with the subclinical form of mastitis (Seegers et al., 2003; Halasa et al., 2007).

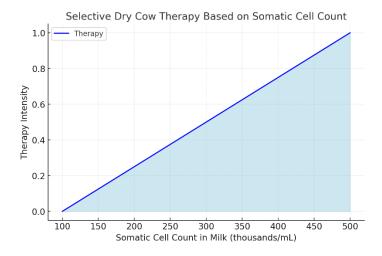
**70% of antibiotics** used in dairy farming are aimed at treating mastitis (van Werven, 2014), of which **40% are used during the dry period** (Kuipers et al., 2016).

### SELECTIVE DRY COW THERAPY (SDCT)

The objective of SDCT is singular:

1. Treat existing infections at the time of transitioning cows to the dry period.

The percentage of cows subjected to such treatment depends on the health status of the herd, which is indirectly linked to the average somatic cell count in the milk.



The chart illustrates **Selective Dry Cow Therapy (SDCT)** intensity as a function of the somatic cell count (SCC) in milk. **Key points from the chart:** 

- The x-axis represents the somatic cell count in milk (thousands per mL).
- The y-axis shows the intensity of therapy.
- As SCC increases from 100,000 to 500,000 cells/mL, the intensity of therapy also increases linearly.
- The shaded area indicates the application range of therapy, with higher SCC requiring more intensive treatment.

This demonstrates that SDCT is proportionally applied based on the SCC levels in milk, aiming to target cows with higher infection risks.

### INTERNATIONAL MASTITIS CONTROL PROGRAMS

- 1. Setting clear goals to ensure udder health.
- 2. Providing a clean, dry, and comfortable environment for cows.
- 3. Following proper milking procedures.
- 4. Ensuring proper maintenance and use of milking equipment.
- 5. Keeping accurate and timely records.
- 6. Effectively managing clinical cases of mastitis during lactation.
- 7. Properly managing dry cows and pregnant heifers.
- 8. Guaranteeing biosecurity against infectious pathogens and culling chronically ill cows.
- 9. Regularly monitoring udder health.
- 10. Periodically reviewing the mastitis control plan.



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**Source:** National Mastitis Council (NMC), <u>official NMC website</u> <u>https://www.nmconline.org/?utm\_source=chatapt.com</u>

### OUTLOOK FOR CHRONICALLY ILL ANIMALS: THE "CHRONIC COW" PROBLEM

- Every farm has a percentage of animals with consistently high somatic cell counts.
- These are often cows missing one or more teats.
- Their history includes multiple episodes of clinical mastitis.
- Usually, they are older animals (more than four lactations).
- Suffering from chronic udder infections caused by various pathogens.
- Udders show varying degrees of anatomical damage.

### SOMATIC CELL ISSUE: A PROBLEM FAR FROM RESOLUTION

- 1. Strict operational protocols.
- 2. Reduction in antibiotic use.
- 3. Use of antibiotics with long withdrawal periods.
- 4. Refusal of therapy.
- 5. Formation of a group of chronic animals.
- 6. Persistent economic losses.

### A NEW SOLUTION FOR DAIRY FARMING

SALVALAT Lavanda Funzionale





- ✓ NOT A MEDICINAL PRODUCT, therefore it is not subject to pharmacological regulations on distribution and use.
- ✓ Has extremely short recommended withdrawal periods.
- Delivers positive results in a high percentage of cases.
- Offers low treatment costs.

### **SALVALAT Lavanda Funzionale**

Reduces or completely eliminates the risk of mastitis becoming chronic, allowing the animal to remain productive in the herd.

Supports effective management of the geometric mean somatic cell count.



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### RECOMMENDATIONS FOR USE

- Perform local **treatment of quarters testing positive for CMT (California Mastitis Test)**, ensuring thorough disinfection of the teat sphincter beforehand.
- Preferably use before the second rise in somatic cell count levels.
- Do not use in cows with acute mastitis



### Salvalat Lavanda Funzionale

With Glycolic Cucumber Extract, pH 5.6



#### **DESCRIPTION:**

**SALVALAT LAVANDA FUNZIONALE**, part of the Animal Health Line, is a functional intramammary rinse of bio-inorganic origin designed for "cleaning and removing" bacterial biofilm formed in the milk ducts and udder cisterns of dairy cows.

This product works locally, providing a surface-level effect without systemic impact. It is not an antibiotic and does not penetrate or spread within the animal's body.

#### SINGLE-USE CATHETER:

The catheter consists of a tube with three openings at the end, inserted into the teat, and a connector that attaches to the bottle dispenser.

#### **INDICATIONS FOR USE:**

For removing bacterial biofilm from the udder of dairy cows.

### METHOD OF APPLICATION:

- 1. Perform the rinse on an emptied udder immediately after milking, having cleaned and disinfected the teat beforehand.
- 2. One rinse per teat.
- 3. Insert the catheter into the teat to a depth of 10–12 cm.
- 4. Avoid contact with the sterile portion of the catheter that enters the
- 5. Residues of the product and biofilm are removed during subsequent milkings.
- 6. Do not use milk obtained within the first 24 hours after treatment.
- 7. Use the entire bottle's contents for each treatment.

**COMPOSITION:** Propylene Glycol, Aqua (Deionized Water), Glycerin, Cucumis Sativus Fruit Extract, Polysorbate 20, PVP.

### PROPELLANT: Nitrogen. CONTRAINDICATIONS:

Known hypersensitivity to any of the product's components.

### POSSIBLÉ SIDE EFFECTS:

The animal may exhibit reactions during treatment. These reactions are not indicative of pain but rather discomfort.

**WARNINGS:** shake the bottle before use. Hold the bottle strictly upright! Incorrect use may reduce product effectiveness. Keep out of reach of children.

STORAGE CONDITIONS: store at a temperature not exceeding 40°C.

**VOLUME:** 100 mL / 150 mL.

**SHELF LIFE:** 24 months from the date of manufacture.

MANUFACTURER: CNT Salus Mundi S.r.l.; Via Cardano 32, 43036 – Fidenza (PR) – ITALY; www.salusthermae.com; info@cntsalusmundi.com; tel.: +39 0524

Everton S.r.l.; Via Azzano 11, 37064 – Povegliano V.se (VR) – ITALY.

**XCLUSIVE DISTRIBUTOR (Italy):** *D.e.r.p.a. Mn-cr S.r.l.*; Via L.Benati 54, 46048 – Roverbella (MN) – ITALY; derpamncr@gmail.com.



Shake the bottle before use. Remove the cap from the SALVALAT Lavanda Funzionale spray bottle and attach the catheter to the bottle dispenser.



Ensure the catheter is securely connected.



Insert the catheter into the teat to a depth of 10–12 cm. Avoid contact with the sterile part of the catheter that enters the teat.

Press the dispenser and use the entire contents of the bottle.



Hold the bottle strictly upright! Improper use may reduce product effectiveness.



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### WHO CAN USE THE PRODUCT

The product is suitable for all farms engaged in milk production, not only for cows but also for sheep and goats.



### **IMPORTANT TO KNOW:**

Table: Milk Losses and Infected Udder Quarters Based on Somatic Cell Count

Somatic Cell Count (per mL)	Milk Loss (%)	Milk Loss per Cow (kg)	% of Infected Udder Quarters
100 000	3	210	6,2
200 000	6	420	7,8
300 000	7	490	9,6
400 000	8	560	12,8
500 000	9	630	16
600 000	10	700	19,2
700 000	11	770	24,3
1 000 000	12	870	32,6

### HOW TO USE THE PRODUCT

Use the product to treat new infections, preventing them from developing into chronic conditions, which are more difficult to manage.

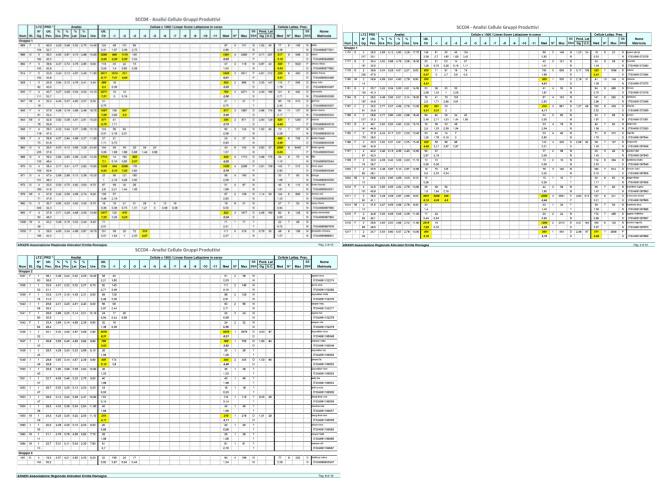
At this stage, microorganisms are still susceptible to treatment, have not yet formed capsules, or developed biofilms

The product may be effective even against microorganisms such as **Staphylococcus aureus** and **Streptococcus uberis**.



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The tables present analyses of somatic cell counts in groups of productive cows. The tables include data on somatic cell counts, milk productivity, and other parameters, categorized by groups.

# ANIMALS SELECTED FOR THERAPY IN FEBRUARY 2022

Nō	Cells	Infected	Micro
	(thousands/μL)	Quarters	organism
206	3717	Front right	Strep.
		quarter (AD)	Uberis
914	3600	Rear left and	Strep.
		right quarters	Uberis
		(PS, PD)	
935	2200	Rear left	Strep.
		quarter (PS)	Uberis
935	1800	All quarters	Strep.
		(AS, PD, PS)	Uberis
1211	3651	Rear quarters	Strep.
		(PS, PD) (+++)	Uberis
1216	2500	Rear left	Strep.
		quarter (PS)	Uberis
1346	3978	All quarters	Strep.
		(AS) (+++)	uberis

### THERAPY RESULTS IN APRIL 2022

Nō	Cells (thousands/µL)	Infected Quarters	Micro organism	Result as of April
206	3717	Front right quarter (AD)	Strep. Uberis	Recovered
914	3600	Rear left and right quarters (PS, PD)	Strep. Uberis	Recovered
935	2200	Rear left quarter (PS)	Strep. Uberis	Recovered but reinfected
935	1800	All quarters (AS, PD, PS)	Strep. Uberis	Recovered
1211	3651	Rear quarters (PS, PD) (+++)	Strep. Uberis	Recovered
1216	2500	Rear left quarter (PS)	Strep. Uberis	Recovered
1346	3978	All quarters (AS) (+++)	Strep. uberis	Still infected



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### Key Abbreviations:

AD — Front right quarter of the udder.

**PS**— Rear left quarter of the udder.

**PD**— Rear right quarter of the udder.

**AS**— All quarters of the udder.

(+++) — High degree of infection.

Strep. uberis — Streptococcus uberis (a bacterium commonly causing mastitis).

zior	e Latta	ar Scor	0 / Line	x 1000	Cellule	1	8 1.37	L. Lan	9	100		si	Analis			PRD *	LTZ		
-10	-9	-8	-7	-6	-5	4	-3	-2	-1	Ult. Ctr	Ure	% Cas	% Lat	% Pro	% Gra	Ult. Pen.	N° Gg	St.	Num
				_		_		2500	691	367	24,70	2,87	4,96	3,72	2,01	26,5	5	F	31
								7,64	5,79	4,88	i					37,9	118		
					43	1515	1252	2025	207	141	26,80	2,73	4,67	3,59	3,24	35,5	4	F	41
					1,78	6,92	6,65	7,34	4,05	3,5	i					33,9	247		
					27	445	146	1791	6065	105	18,40	3,08	4,68	4,02	3,87	25,0	7	F	106
	1,11	5,15	3,55	7,16	8,92	3,07						33,6	235						
							354	3717	367	101	20,90	2,99	4,82	3,87	4,05	32,5	2	G	206
							4,82	8,22	4,88	3,01						30,9	140	$\perp$	
						14	10	2271	68	1141	14,60	2,59	4,72	3,28	3,48	33,2	4	F	935
						0,16	0	7,51	2,44	6,51						41,1	192		
						470	120	1877	112	249	15,50	2,70	5,06	3,41	4,84	28,6	4	F	993
						5,23	3,26	7,23	3,16	4,32						33,3	174		
						246	3258	3651	3205	61	19,90	2,67	4,98	3,30	3,75	32,7	2	G	1211
						4,3	8,03	8,19	8	2,29						36,6	173		
		1	_				18	2515	417	141	19,70	2,64	4.76	3,32	4,36	29,2	2	G	1216
							0,53	7,65	5,06	3,5						41,5	169		
		1	_					3978	835	545	15,40	2.96	4,97	3,81	4,53	30.4	1	F	1346
			_					8,31	6,06	5,45	.0,40	2,00	7,07	5,01	1,00	29,8	113	ŕ	

### **CONCLUSION:**

In conclusion, the systematic use of **Salvalat Lavanda Funzionale**, combined with proper milking techniques and maintenance of milking equipment, is a key factor in maintaining udder health in dairy cows.

The long-term effectiveness of this product is demonstrated by tangible benefits, such as reducing the culling of animals due to chronic mastitis and keeping somatic cell counts below the critical threshold of 200,000.

These benefits result in significant reductions in economic losses, considering that a cow with high somatic cell counts during lactation may produce 500–700 liters less milk and may require replacement with a heifer, which typically costs around €2,500.

Thus, the use of **Salvalat Lavanda Funzionale** and the implementation of appropriate management practices are a valuable investment that ensures udder health in cows and optimizes the economic efficiency of livestock operations.

### MILKING PROCESS FLOWCHART



Preparation Time for Milking: 90–120 second



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### STEP 1: STRIPPING



STRIPPING
As the first step, perform at least 5–6 stripping actions for each teat.
This helps identify animals with altered milk consistency, poor milk quality, or other issues.

### STEP 2: DISINFECTION



DISINFECTION
Treat the teats with a disinfectant solution to ensure cleanliness and reduce bacterial contamination.

### STEP 3: DRYING



**DRYING**Gently dry the teats with a clean towel to prepare them for milking.

### STEP 4: ATTACHMENT



ATTACHMENT
Securely attach the
milking equipment to
the teats, ensuring
proper alignment and
vacuum levels

STEP 5: POST-MILKING DISINFECTION



POST-MILKING DISINFECTION Apply a disinfectant to the teats after milking to prevent infections and promote udder health.

### INNOVATIONS AND DEVELOPMENT IN LIVESTOCK MANAGEMENT

Welcome to our company. We are proud to introduce our **Research and Development Division**, dedicated to enhancing and creating solutions for farmers and livestock professionals.

Our division conducts thorough research and testing, combining theoretical and practical approaches to achieve high-quality products. Additionally, we collaborate with independent laboratories to obtain necessary certifications, ensuring the safety and reliability of our solutions.

We extend our gratitude to veterinarians *Giuseppe Orsi* and *Marzio Schianchi* for their contributions to the development and support of these projects. Their expertise in herd management, prophylaxis, CNCPS nutrition, hygiene, and milk quality has made these initiatives possible.

We are confident that our solutions will help improve livestock management and animal health while optimizing the efficiency of farming operations.

Thank you for your attention! We are always available to provide further information about our products and initiatives.

Clusternanotech Group, in collaboration with DOTT. GIUSEPPE ORSI (Management of the herd, prophylaxis, CNCPS nutrition, hygiene, and milk quality) and DOTT. SCHIANCHI MARZIO (Veterinary LP).