SAFETY DATA SHEET
DS34 Spray

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE OF THE COMPANY/UNDERTAKING

1.1 Product identification	Class IIb medical device - CE 0546 Dir 2007/47/EEC
1.2 Relevant uses of the substance or mixture and recommended uses	Powder sterilizer to be diluted in water for rapid sterilization of invasive and non-invasive medical devices and small surfaces. Professional use
1.3 Distributor Identification	G.COMM Srl – via XXV Aprile, 20 20884 Sulbiate (MB) Italy - tel/fax +39 039 6060420
1.4 Manufacturer	ICM S.r.l.
1.5 Emergency telephone number	For urgent information please contact: "CENTRO ANTIVELENI" - Osp. Niguarda - Milan Specialized for chemical poisoning - Tel. 02 66101029

2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP) and subsequent amendments and adjustments. The product therefore requires a safety data sheet in accordance with the provisions of Regulation (EC) 1907/2006 and subsequent amendments.
Any additional information regarding the risks to health and/or the environment is given in section 11 and 12 of this card.

Acute toxicity, category 4 H304 may be fatal if ingested
Skin irritation, category 2 H315 causes skin irritation
Serious eye injuries, category 1 H318 causes serious eye injuries
Irritation of the respiratory tract H335 may irritate the respiratory tract
Dangerous for the aquatic environment, chronic toxicity, category 3 H 412 harmful to aquatic organisms

2.2 Label elements

Pictograms



The powdered product can be lethal **if ingested**

Indications of danger

Ingestion	The powdered product can be lethal if ingested H304
Skin contact	Causes skin irritation H315 • Contact of the powdered product with wet skin causes irritation. It's water-reactive. • Contact of the solution with the skin at the intended concentrations of use does not cause irritation.
Eye contact	Causes serious eye injuries H318
Inhalation	May irritate the respiratory tract H335 • The powdered product is irritating to the respiratory tract: in contact with humidity it releases toxic vapours (bromine). *The powdered product is packaged in single-dose glass vials (max dose g 7/flacon); under normal conditions of use and in compliance with the instructions for use shown on the label, it does not emit hazardous vapours and is not irritating to the*

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	respiratory tract. • The solution at the intended use concentrations is odourless; it does not emit hazardous vapours into the working environment.

Cautionary advice
P102 keep out of reach of children.
P232 protect from moisture.
P220 keep away from combustible materials.
P262 avoid contact with skin and eyes.
P305/P351/P313 in case of contact with eyes rinse thoroughly with water and seek medical advice.
P301/P312 if swallowed or if you feel unwell seek medical advice immediately.
P235 store in a cool place.
P273 do not disperse into the environment.

2.3 Other hazards
No data available

3. COMPOSITION/INFORMATION ON COMPONENTS

Composition of the powder formulation: Sulphate peroxides - sodium bromide buffered with alkaline carbonates
Sodium Bromide classified as non-hazardous under the provisions of Regulation (EU) 1272/2008 (CLP).
Sulphate peroxides and alkaline carbonates classified as dangerous under the provisions of Regulation (EU) 1272/2008 (CLP).

Composition of the active solution	0.45%:
Br- as sodium bromide	0.096%
SO4-- as sodium sulfite	0.12%
Chemical degradation products:	Li^+ - B^{---} - Na^+ - K^+ - CO_2^{--}
	H_2O q.b. a 100

The full text of the hazard statements (H) is given in section 15.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General information	See a doctor. Show this safety data sheet to your doctor.
In case of inhalation	Take to a well-ventilated place and let it breathe deeply. See a doctor if the discomfort persists.
In case of skin contact	Wash immediately and thoroughly with water
In case of eye contact	Wash immediately and abundantly with water, holding the eyelids wide open until the symptoms disappear and then with the decongestant ophthalmic solution, undergo a specialist examination.
Ingestion	Seek medical attention immediately. Stop in a ventilated area.

4.2 Main symptoms and effects, both acute and delayed.
No data available.

4.3 Indication of any immediate medical attention and special treatment needed.
No data available.

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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media
The means of extinction are the traditional ones: Water, foam, extinguishing powder.

5.2 Special hazards arising from the substance or mixture
In contact with moisture, the powdered product emits toxic fumes (bromine).

5.3 Recommendations for firefighters
Wear respiratory protective equipment, visors and gloves.

6. MEASURES IN CASE OF ACCIDENTAL RELEASE

6.1 Personal precautions, protective equipment and emergency procedures
Wear protective clothing, combined filter mask and goggles.

6.2 Environmental precautions
Cutting the leak. Prevent the product from reaching watercourses and/or dispersing underground. Prevent product from entering sewers, surface water, ground water.

6.3 Methods and materials for the containment of remediation
Vacuum the spilled product into a suitable container. Provide sufficient ventilation of the environment. Pour abundant amounts of water (in a ratio of approx. 1:1000) on the product residue.

6.4 References to other sections
Information on personal protection and disposal is given in sections 8 and 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with eyes and skin. Keep away from heat sources.
The powdered product is packaged in single-dose glass vials; under normal conditions of use and in compliance with the following requirements
the instructions for use on the label do not require special precautions.

7.2 Conditions for safe storage, including any incompatibilities
Store only in the original container. Store in a dry and ventilated place. Keep containers tightly sealed. Avoid direct exposure to sunlight.

7.3 Special end uses
No data available.

8. EXPOSURE CONTROL / INDIVIDUAL PROTECTION

8.1 Control parameters
Does not contain substances with an occupational exposure limit value

8.2 Exposure controls

Suitable technical checks	Observe the usual safety measures when handling chemicals.
Eye/face protection	Wear safety glasses
Hand protection	Protect hands with work gloves
Skin protection	Wear long-sleeved work clothes
Respiratory protection	Mask with combined filter in case of emergency (Ref. standards EN 14387 and/or EN 143).

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Dust
Colour	White
Smell	Odourless
Olfactory threshold	ND
PH of the active solution	8.5/9.5
Melting or freezing point	ND
Initial boiling point and boiling range	ND
Flashpoint	ND
Evaporation rate	ND
Flammability of solids and gases	ND
Lower flammability limit	ND
Upper flammability limit	ND
Lower explosive limit	ND
Upper explosive limit	ND
Steam tension	ND
Vapour density	ND
Solubility	Soluble in water
Partition coefficient: n-octanol/water	ND
Auto-ignition temperature	ND
Decomposition temperature	Self-accelerating decomposition possible at temperatures from approx. 80°C. Remarkable decomposition at temperatures > 60°C
viscosity	ND
Explosive properties	ND
Oxidizing properties	NO

9.2 Other information
No data available.

10. STABILITY AND RESPONSIVENESS

10.1 Reactivity
There is no particular danger of reaction with other substances under normal conditions of use.

10.2 Chemical stability
The product is stable when kept under normal conditions of use and storage.

10.3 Possibility of dangerous reactions
None under normal conditions of use and storage. The contact of the powdered product with liquid substances or with the humidity of the air gives rise to reactions with the emission of toxic vapours, in particular bromine.

10.4 Conditions to avoid
Avoid direct exposure to heat and sunlight. Keep the container sealed to avoid contact of dust with air humidity.

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10.5 Incompatible materials
It's an inert anhydrous powder. The contact of the powdered product with liquid substances or with the humidity of the air gives rise to reactions with emission of toxic vapours (bromine).

10.6 Hazardous decomposition products
Carbon dioxide. Bromo. Oxygen

11. TOXICOLOGICAL INFORMATION

In the absence of experimental toxicological data on the product, any health hazards have been assessed based on the properties of the components. The concentration of the individual hazardous components should therefore be considered in order to assess the toxicological effects resulting from exposure to the product.
Acute effects: The powdered product can be fatal if ingested; contact with the eyes can cause serious eye injury.
The powdered product may cause sensitization if the skin is wet; in case of absorption of moisture it causes reactions with emission of toxic vapours (bromine), and therefore in this case it may cause irritation to the respiratory tract.
The active solution does not cause sensitization or intolerance to the skin and respiratory tract.

The powdered product is packaged in single-dose glass vials (max dose g 7/flacon); under normal conditions of use and in compliance with the instructions for use shown on the label, it does not emit dangerous vapours, is not irritating to the respiratory tract and does not come into contact with the skin.

11.1 Acute toxicity related to the most critical components:

Acute toxicity sodium bromide	DL50. oral (rat) 3500 mg/kg
Acute peroxide sulphate toxicity	LD50 - oral (rat) 1000/2000 mg/kg LD50 - skin (rabbit) 2000 mg/kg

11.1.2 Mixture

Acute inhalation toxicity	ND
Acute oral toxicity	It can be lethal if ingested
Acute skin toxicity	ND
Skin corrosion/irritation	ND
Severe eye injury/serious eye irritation	Causes serious eye injuries
Respiratory or skin sensitization	ND
Carcinogenicity	ND
Germ cell mutagenicity	ND
Reproductive toxicity	ND
Specific target organ toxicity (single exposure)	ND
Specific target organ toxicity (repeated exposure)	ND
Danger in case of aspiration	ND

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12. ECOLOGICAL INFORMATION

12.1 Toxicity
The product is toxic to aquatic organisms. Use according to good working practices, avoiding to disperse the product in the environment.

12.2 Persistence and degradability
No data available

12.3 Bioaccumulation potential
No data available.

12.4 Mobility in the soil
No data available.

12.5 Results of PBT and vPvB assessment
No data available

12.6 Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Product	Dispose of as special waste in accordance with local and national legislation.
Solution	The solution respects the limits for discharges into the sewer system.
Containers	After proper washing treatment, they can be assimilated to municipal waste. In any case, do not disperse into the environment after use.

14. TRANSPORT INFORMATION

14.1 UN number
ADR / RID, IMDG, IATA — A 3134

14.2 UN proper shipping name

sturdy (*inorganic)* water-responsive *(basic)*poisonous
The powdered product if it comes into contact with moisture air or with liquid substances give off toxic vapours (bromine).

14.3 Transport hazard classes
ADR / RID, IMDG, IATA — Class 4.3 (6.1)

14.4 Packing group
ADR / RID, IMDG, IATA — II

14.5 Environmental hazards
ADR / RID — NO

14.6 Special precautions for users
The product, in contact with the humidity of the air, develops toxic gases
ADR / RID Nr Kemler: 462 — Maximum quantity: g. 500

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IMDG	EMS: F-G S-N	Limited Quantities: g. 500
IATA		LTD QTY Packing Instruction: Y474 LTD QTY Max: Kg 1 Passenger Air Packing Instruction: 483 Passenger Air Max: Kg 15

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Dangerous Preparations Directive 1999/45/EC. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Regulation (EEC) No. 793/93 and Council Regulation (EC) No. 1488/94 and Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006 and subsequent amendments.

Labelling D.L. 65	According to EEC Directive 91/155/EEC, 67/548/EEC and subsequent amendments of 14/03/2003 and subsequent supplements)
Indications of danger H injury	H304: May be fatal if ingested. H315/H319/H335: causes skin irritation, severe eye irritation; may irritate the respiratory tract. H318: causes serious eye . H412: Harmful to aquatic organisms.
Cautionary advice P	P102: Keep out of reach of children. P232: protect against moisture. P220: keep away from combustible materials. P262: Avoid contact with skin and the eyes. P305/P351/P313: in case of contact with eyes rinse out carefully with water and consult a doctor. P301/P312 if swallowed or if you feel unwell seek medical advice immediately. P235 store in a cool place. P273: Do not disperse into the environment.
Warnings	The product must be used by qualified personnel. Store in a dry place at room temperature and away from heat sources. The expiry date refers to product correctly stored and intact, in its original packaging.

16. OTHER INFORMATION

The information in this MSDS is based on the current state of knowledge at the moment of the last revision. Use as described on the label is recommended. The use of the product in combination with any other product or in any case under conditions other than those indicated on the label, it becomes sole responsibility of the user. It is the user's responsibility to comply with the laws and regulations of the existing health and safety provisions. This safety data sheet has been prepared for storage, the safe transport and use of the product. Any other use of the product in combination with or in others processes take place at your own risk.

REV	DATE	Reason for revision
3	29/05/20	Points: 2.2 – 6.1 – 7.1 – 11

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TECHNICAL DATA SHEET

NAME: DS34

- Rapid Sterilizer Spray for devices and small surfaces. Free radical generator.
MEDICAL DEVICE CE 0546
Class IIb medical device
No. Medical Devices Repertoire:
- Code 5230/26 : 1538206
- Code 5230/15 : 1814815

PRESENTATION FORM: white powder.

STANDARD DOSE OF USE: 0.45% (g4.5 per litre of water)
- g 3,4 per 750 ml of water

COMPOSITION: buffered oxidizers + activators

SOLUBILITY IN WATER: soluble.

PH VALUE at 20° C of the active solution: 8,5/ 9,5

DUST STABILITY: the product is stable 24 months if stored under normal conditions, in environments ventilated and away from excessive heat; it is particularly afraid of humidity.

FIELDS OF APPLICATION:
Rapid sterilization of small surfaces such as operating tables, dental units, instrument trays, medical equipment; invasive and non-invasive medical devices.

MICROBIOLOGICAL CHARACTERISTICS:
Active ingredient: free radicals with reducing character.
Mechanism of action: Transfer of electrons that react with the structure of pathogenic microorganisms causing irreversible chemical damage and their immediate destruction.

Activity: gram+ and gram- bacteria; viruses (including HIV-HBV-HCV); tuberculosis mycobacterium; fungi.
Activity times:
Sterilization: Five seconds.
The solution can break down $8\log_{10}$ of spores bacillus subtilis with a 5 second contact.

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Spore activity of Bacillus Subtilis ATCC 19695 Initial suspension: 8log$_{10}$ UFC/ml Dose of application: 0,35%		
ANALYTICAL RESULTS		
Contact times	**Test Name and Analytical Method**	**Spores shot down**
2 seconds	Sporicidal activity UN EN 13704:2005	8log$_{10}$ UFC/ml

Spore activity of Bacillus Subtilis ATCC 6633 Initial suspension: 8log10 UFC/ml Dose of application: 0,25%		
ANALYTICAL RESULTS		
Contact times	**Test Name and Analytical Method**	**Spores shot down**
5 seconds	Sporicidal activity UN EN 13704:2005	8log$_{10}$ UFC/ml

PROPERTIES AND BENEFITS:

- Sterilizes treated surfaces and devices within seconds; prevents the risk of infection for the operator because it inactivates pathogenic microorganisms on simple contact and prevents their migration.
- The basic pH values and the reducing activity of radicals prevent oxidation phenomena and do not compromise the integrity of surfaces and instruments. It doesn't stain, it doesn't leave halos.
- The single-dose bottle facilitates the preparation of the active solution; the powder is directly solubilized in the 750 ml bottle equipped with a spray dispenser.
- The dust dissolves in mains water at room temperature. The ready-to-use solution takes on a soft yellow colour that confirms to the operator the beginning of the sterilizing activity.
- The solution is odourless and does not emit hazardous vapours into the working environment.
- Accidental contact of the solution or dust with the skin does not cause irritation (contact of dust with wet or damp skin may cause irritation).
- The exhausted solution respects the legal limits for discharge into the sewer system.

INSTRUCTIONS FOR USE:

Preparing the solution:

- Fill the 750 ml **bottle B** with water. Only mains water at room temperature is sufficient.
- Transfer the powder contained in **vial A** from g 2.6 to vial **B.**
- Close the bottle B with the spray nozzle and shake well to facilitate the dissolution of the powder.
- Wait about 10 minutes; the solution will have the characteristic pale yellow colour which confirms the start of the sterilizing activity. (If the mains water is harder than 20°F the solution may appear cloudy).
- The solution thus obtained is active and ready to use, and is valid 7 days after preparation.

Sterilisation of surfaces:

- - Thoroughly irrigate the devices and surfaces to be sterilized.
- - Wait for activity time and dry (5 seconds).

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NB:
Once the active solution has been prepared, before use, write in the appropriate spaces on the 750 ml bottle "B" the following data:
(1) batch No of the powdered product on vial 'A' of g 2,6.
2) expiry date of the active and ready to use solution (valid 7 days after preparation).

TRACEABILITY OF THE STERILIZATIONPROCESS
Once the sterilization solution has been prepared, you can remove the label from the bottle and apply it to the register to allow traceability of the sterilization process.

STABILITY OF THE ACTIVE SOLUTION: 7 days

DEADLINE: Dust validity 24 months

MANUFACTURING PROCESS: According to a technical file prepared with the indication of the instructions operative. All the operations inherent to the manufacturing process, from the receipt of the raw materials to the storage of the finished product, are carried out according to the Quality Management System implemented in compliance with the following requirements to UNI EN ISO 9001 and UNI EN ISO 13485 standards.
MANUFACTURER: ICM S.r.l.

QUALITY CONTROL:
FIRST MATERIALS: physical checks and percentage of active substances.
PACKAGING MATERIAL: physical checks.
CONTROLS IN THE PROGRESS OF PRODUCTION: appearance and organoleptic characteristics, density, pH, activity control reducing agent, theoretical and practical performance, quality standard verification of the package, lot identity.

STORAGE MODE: Store at a temperature between 5° and 40° in a dry and ventilated environment steady.

RAW**MATERIALS USED FOR PRODUCT REALIZATION:** high quality raw materials purity.

NATURE OF THE PACK: glass vial with sealed capsule.

CONFIRMATION OF VALIDITY IN TIME: on batches taken from samples, periodically, the following power is determined reducing agent, until the expiry date shown on the label.

METHODS FOR DISPOSAL: the product in the dilutions of use respects the limits of the law for the introduction into the sewer system.

PACKAGES:
- 3.4 g vial (0.75 litres of solution) DS34 Pack of 12 vials

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REV	DATE	Reason for revision
2	29/05/20	Standard dosage - Instructions for use - Packaging

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CERTIFICATO CE - SISTEMA COMPLETO DI GARANZIA DI QUALITÀ

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

ICM S.R.L.

IT – 89040 PORTIGLIOLA (RC) – CONTRADA TORRE QUOTE SAN FRANCESCO SN

SITI / SITES

IT – 89040 PORTIGLIOLA (RC) – CONTRADA TORRE QUOTE SAN FRANCESCO SN

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / *FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES*

Disinfettanti e sterilizzanti per dispositivi medici invasivi e non invasivi.

Disinfectants and sterilants for invasive and non-invasive medical devices.

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato **II** ad esclusione del punto 4
is in compliance with the requirements of Directive 93/42/EEC, Annex *excluding section 4*

RAPPORTO DI AUDIT N° *AUDIT REPORT NO.* **12260/2**

CERTIFICATO N. *CERTIFICATE N.* **12260/2**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITA' AI SENSI DELLA DIRETTIVA 93/42/CEE. Il SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA.

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDING AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC. THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

PER L'IMMISSIONE IN COMMERCIO DEI DISPOSITIVI DI CLASSE III OGGETTO DEL PRESENTE CERTIFICATO, E' RICHIESTO UN CERTIFICATO ADDIZIONALE IN ACCORDO ALLA DIRETTIVA 93/42/CEE ALLEGATO II (4)

FOR THE PLACING ON THE MARKET OF CLASS III DEVICES COVERED BY THIS CERTIFICATE, AN EC DESIGN-EXAMINATION CERTIFICATE ACCORDING TO DIRECTIVE 93/42/CEE ANNEX II (4) IS REQUIRED

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE.

THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICE IN CLASSE I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO

THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE *FIRST ISSUE* 03/08/2017

EMISSIONE CORRENTE *CURRENT ISSUE* 24/05/2021

DATA DI SCADENZA *EXPIRY DATE* 02/08/2022

IL PRESIDENTE - CESARE PUCCIONI

Mod. C 93-42 II ED 00 010820

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. **12260/2**

ANNEX TO CERTIFICATE N.

ICM S.R.L.

SITI / *SITES*

IT – 89040 PORTIGLIOLA (RC) – CONTRADA TORRE QUOTE SAN FRANCESCO SN

ELENCO PRODOTTI / *PRODUCT LIST*

DIAL
EC-STER
EC STER SPRAY

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE *FIRST ISSUE* 03/08/2017

EMISSIONE CORRENTE *CURRENT ISSUE* 24/05/2021

DATA DI SCADENZA *EXPIRY DATE* 02/08/2022

IL PRESIDENTE – CESARE PUCCIONI

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
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