

BATCH INFORMATION / BATCH RELEASE DECLARATION OF CONFORMITY

Name and Address of Manufacturer SOFAR SPA VIA FIRENZE 40
20060 – TREZZANO ROSA – MI -

Product KLISTIER H

Batch Number FRESENIUS / SOFAR 50210396/210396

Packing Size, Packaging Material 130 ML BOTTLE

Article-No.-FRESENIUS KABI 1991081

Article-No. SOFAR 10001006

Date of Manufacture 05/2021

Expiry Date 05/2024

Batch Size (planned amount in l or kg) 9.000 LITERS

Filled Units (pieces) 68.652 PCS

Samples (pieces or %), 52 PCS
of that **Samples for FRESENIUS KABI** (pieces)

Reject Rate (pieces and % of the filled units) _____

Released Amount (pieces of sales ware) 68.600 PCS

Remarks on Deviations in Manufacturing and Control:

We hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provision of Directive 93/42/EEC, as amended by 2007/47/EC, and its transposition into national laws. The products comply with the essential requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Attachments (please mark)

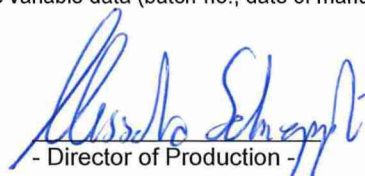
- ☒ **Certificate of Analysis¹⁾**
- ☐ **Label container²⁾** (Original)
- ☐ **Label carton²⁾** (Original)
- ☐ **Label folding carton²⁾** (Original)
- ☐ **Leaflet** (Original)

¹⁾ according to the specification of the control on finished product, including a remark if the batch is conform

²⁾ with correct imprint of the variable data (batch-no., date of manufacture (if applicable), expiry date)

Date: 15/06/2021

Released:


- Director of Production -


- Director of Quality Control -



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Capitale Sociale interamente versato €1.300.000,00
Codice Fiscale, numero di iscrizione registro imprese e partita iva 03428610152
REA 852745 – Meccanografico MI 108973
Sede Legale e Operativa: Via Firenze, 40 – 20060 Trezzano Rosa (MI)

CERTIFICATO ANALITICO

No. PF.21.00494

Codice Prodotto 10001006	Descrizione Prodotto KLISTIER 130ml D		Lotto 50210396
Data di fabbricazione	05/2021	Data di scadenza	05/2024
Metodo d'analisi	PF015 Rev 10	Numero d'analisi	C/43154

Saggio	Specifica	Risultato	Giudizio
Appearance	Clear and colourless solution	Clear and colourless solution	CONFORME
Mean volume	124 - 136 ml	131 ml	CONFORME
Volume uniformity	Average volume +/- 10%	Complies	CONFORME
Relative density	1,123-1,135	1,126	CONFORME
pH	5,0-5,8	5,4	CONFORME
Identification sodium	Positive	Positive	CONFORME
Identification phosphate	Positive	Positive	CONFORME
Sodium dihydrogenphosphate	13,22-14,61 g/100 ml	13,80 g/100 ml	CONFORME
Disodium hydrogenphosphate	3,02-3,34 g/100 ml	3,19 g/100 ml	CONFORME
Sodium benzoate	95,0-105,0 mg/100 ml	99,2 mg/100 ml	CONFORME
Methyl parahydroxybenzoate	47,5-52,5 mg/100 ml	49,6 mg/100 ml	CONFORME
Total bacteria count	Max 100 ufc/ml	< 10 ufc/ml	CONFORME
Total fungi count	Max 10 ufc/ml	< 10 ufc/ml	CONFORME
Escherichia coli	Absent	Absent	CONFORME
Salmonella	Absent	Absent	CONFORME
Pseudomonas aeruginosa	Absent	Absent	CONFORME
Staphylococcus aureus	Absent	Absent	CONFORME

**CONFORMS
TO THE
ORIGINAL**

Data 15/06/2021 9.47	Giudizio CONFORME	Responsabile C.Q. DAVIDE RESNATI
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