Night Cleaner - Composition

Based on available documentation from ALPRO MEDICAL GMBH:

- Bilpron Statement composition dated of 09.05.2018, in appendix
- Declaration of Identity dated of 24 October 2018, in appendix

E.M.S Electro Medical Systems S.A, can declare that Night Cleaner (DV-154), manufactured by ALPRO MEDICAL GMBH, is composed of the following ingredients and does not have any other composition.

Component	CAS number	Exact content
1,2 – propylenglycol	57-55-6	Confidential
EDTA	139-33-3	Confidential
Phenoxyethanol	122-99-6	Confidential
Parabens		
- Methylparaben	99-76-3	Confidential
- n-Butylparaben	94-26-8	Connuential
- Ethylparaben	120-47-8	
Polyaminopropyl-biguanide	32289-58-0	<0.2%
Aroma	5989-27-5	<0.2%
Water	7732-18-5	Confidential

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ALPRO MEDICAL GMBH Mooswiesenstr. 9, D-78112 St.Georgen Germany

Bilpron

Component	CAS number	Exact content
1,2 - propylenglycol	57-55-6	Confidential
EDTA	139-33-3	Confidential
Phenoxyethanol	122-99-6	Confidential
Parabens - Methylparaben - n-Butylparaben - Ethylparaben	99-76-3 94-26-8 120-47-8	Confidential
Polyaminopropyl-biguanide	32289-58-0	< 0.2 %
Aroma: mixture, containing apple-aroma + d-limonen, natural	5989-27-5	< 0.2 %
Water	7732-18-5	Confidential

We, ALPRO MEDICAL GMBH, certify that the above product is composed of the following ingredients and does not have any other composition.

Sincerely yours,

Name: Werner Rösner Name of Department: R & D Manager, Chemist MSc Date: 09.05.2018

pp Werner Rösne

ALPRO MEDICAL GMBH Mooswiasenstraße 9 D-78112 St. Ceorgen Germany Tel. 07725/9392-0 Fax 9392-91

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Statement by R & D



Declaration of Identity:

The preparation

NIGHT CLEANER

distributed by company E.M.S. Electro Medical Systems S.A., is a cleaning and disinfection solution ready for use for the water lines of all EMS AIRFLOW devices. Its formulation is identical with the ALPRO preparation **Bilpron**.

The manufacturing, filling and packaging of NIGHT CLEANER and Bilpron is executed at ALPRO under equal conditions and are subject to the implemented QM system according to DIN EN ISO 13485:2016.

Thus, a direct transferability of clinical data, material tests, approvals and application recommendations is given.

pp. Werner Rösner Chemist, R&D Dept. ALFRO MEDIOAL CORD Money is son straße 9 D-7312 St. Georgen Germany Tel. 07725/0352-0 Fax (0322-91

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as at: 24 October 2018 – WR/cw

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All dates and times are in UTC+01:00.

PU FE-1005 Night Cleaner Composition

Collaboration après refus

Name/Signature	Title	Date	Meaning/Reason
Margaux Janier (MJN)		20 Nov 2018, 11:43:30 AM	Complete

Author and reviewers

Name/Signature	Title	Date	Meaning/Reason
Margaux Janier (MJN)		20 Nov 2018, 11:49:39 AM	Approved

final review

Name/Signature	Title	Date	Meaning/Reason
Gaelle Pacaud (GPC)		29 Nov 2018, 04:57:39 PM	Approved

approval

Name/Signature	Title	Date	Meaning/Reason
Timothée Deblock (TDE)		02 Dec 2018, 04:15:03 PM	Approved

Notification and update ERP

Name/Signature	Title	Date	Meaning/Reason
Generic user Notificator (NOTIFICATOR)		02 Dec 2018, 04:15:04 PM	Email Sent