

DECLARATION OF CONFORMITY

According to the prescription of REACH REGULATION (1907/2006/EC)

**To Our Valued Customers,
and whoever is concerned:**

Based on the information transmitted to date by our suppliers, in accordance with article 33 of Regulation (EC) 1907/2006 (REACH), FLAEM NUOVA Spa declares that some of the articles supplied contain SVHC substances (Substances of Very High Concern) , included in the Candidate List, update to 21st January 2025, including 247 substances, in a concentration higher than 0,1% weight/weight.

The Candidate List can be consulted on the ECHA website at the following address:
<https://echa.europa.eu/it/candidate-list-table>,

The detailed list is reported as below:

Article	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
Piston aerosol, excluded type F2000	Lead	7439-92-1	>0,1% w/w	Brass motor eccentric joint
Suction units (AR..., AS...)	Lead	7439-92-1	>0,1% w/w	
Vacuum Sealers	Lead	7439-92-1	>0,1% w/w	
Respiratory physiotherapy devices	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
SFG62	LIFE PRO SFIGMO BRAC.AUT.TMB-1490CS	Lead	7439-92-1	>0,1% w/w	Steel magnetic Valve
SFG61	LIFE EVO SFIGMO BRAC.AUT.TMB-1491S	Lead	7439-92-1	>0,1% w/w	
SFG60	SFIGMO MC PULS.TMB-1112)'17 1% FOC	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
TRM04 TRM07 TRM12	DIGITAL THERMOMETER	Lead oxide	1317-36-8	>0,1% w/w	Buzzer ceramics
		Lead Tetroxide	1314-41-6	>0,1% w/w	
		Trilead bis(carbonate) dihydroxide (basic lead carbonate)	1319-46-6	>0,1% w/w	
		Pyrochlore, antimony lead yellow	8012-00-8	>0,1% w/w	
		Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
VB13PK1	TEKNA MV 230/50	Lead	7439-92-1	>0,1% w/w	Cable pins (Brass)
VB14PK1	MINIVAC BERK.	Lead	7439-92-1	>0,1% w/w	
VDXX..	MAGIC VAC MAXIMA 2/ AXOLUTE /BERK	Lead	7439-92-1	>0,1% w/w	
V972PK1	VANTAGE MV KIT 230/50 (4)	Lead	7439-92-1	>0,1% w/w	
VEXX..	MAGIC VAC ELITE 300 PLUS	Lead	7439-92-1	>0,1% w/w	
V7XX..	MAGIC VAC PROFESSIONAL JUMBO 30- JUMBO 30 PLUS/ JUMBO 30 EVO	Lead	7439-92-1	>0,1% w/w	
IT00E00	TABITHERMAE INALA.TERM.230V50HZ WHITE MED	Lead	7439-92-1	>0,1% w/w	
NS03P00	NEO SPIRE UK	Lead	7439-92-1	>0,1% w/w	
VI07P00	PULMOWAVES PRO LINE 230V 50HZ UK BREXIT	Lead	7439-92-1	>0,1% w/w	
CF11P00	AR 4NEB 230/50 P20 UK (8) TUV	Lead	7439-92-1	>0,1% w/w	
ELXX	AEROSOL PISTONE TIPO ELISIR	Lead	7439-92-1	>0,1% w/w	
FJ59P00	AR DUO F400 230V 50HZ UK (6) TUV	Lead	7439-92-1	>0,1% w/w	
FU03P00	AR RESPIRAIR F1000 UK 230/50 (6)	Lead	7439-92-1	>0,1% w/w	
SA07P00	AR GHIBLI PLUS F400 230V50HZ UK (8) TUV	Lead	7439-92-1	>0,1% w/w	
SCXX...	AEROSOL PISTONE	Lead	7439-92-1	>0,1% w/w	
NA16P00	AR AERO-NEB PROFESSIONAL 230V AUS VERIFICARE VESTI	Lead	7439-92-1	>0,1% w/w	
PT10P00	AR AERO-NEB MASTER F400 230V BLU TUV OK	Lead	7439-92-1	>0,1% w/w	
AP5XX...	AR AIR PRO F3000	Lead	7439-92-1	>0,1% w/w	
ASXX ..	AS ASPIRA PLUS	Lead	7439-92-1	>0,1% w/w	
AR2XX..	AS ASPIRA GO 20 LT	Lead	7439-92-1	>0,1% w/w	
AR3XX..	AS ASPIRA GO 30 LT	Lead	7439-92-1	>0,1% w/w	
SPXX..	AS SUCTION PRO DP	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
FUXX..	AEROSOL A PISTONE TIPO RESPIRAIR	N-metil pirrolidone	872-50-4	>0,1% w/w	Avvolgimento del motore
DRXX...	DOCCE NASALI MOBILE, DOCCE NASALI SPRINT	N-metil pirrolidone	872-50-4	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
AR2XX..	AS ASPIRA GO 20 LT	lead zirconium titanate	12626-81-2	>0,1% w/w	Buzzer ceramics
AR3XX..	AS ASPIRA GO 30 LT	lead zirconium titanate	12626-81-2	>0,1% w/w	
ACO001C	TESTA DI NEBULIZZ. COMPL. MF32E00	Lead	7439-92-1	>0,1% w/w	
ACO377P	SET BATTERIE LI-ION WI-NEB	Lead	7439-92-1	>0,1% w/w	
ACO747P	R69430M ELECTR.CONTR.BOARD X 69430	Lead	7439-92-1	>0,1% w/w	
ALXX..	AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
AN03P00	AR ALPHANE 400 230V50 P20 AZZ. ECO	Lead	7439-92-1	>0,1% w/w	
COXX..	AR COCCINELLA / BEETLE	Lead	7439-92-1	>0,1% w/w	
DRXX	NE RHINO CLEAR MOBILE	Lead	7439-92-1	>0,1% w/w	
HN08P00	AR INHALATOR T2000 230/50	Lead	7439-92-1	>0,1% w/w	
IT00E00	TABITHERMAE INALA.TERM.230V50HZ	Lead	7439-92-1	>0,1% w/w	
JNXX..	AR AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
MFXX	AEROSOL ELETTRONICI	Lead	7439-92-1	>0,1% w/w	
MIXX..	AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
MNXX..	AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
NAXX..	AEROSOL PISTONE	Lead	7439-92-1	>0,1% w/w	
OD01P00	OXYLAST MED EASY	Lead	7439-92-1	>0,1% w/w	
PNXX	AEROSOL PISTONE	Lead	7439-92-1	>0,1% w/w	
PT10P00	AR AERO-NEB MASTER F400 230V BLU	Lead	7439-92-1	>0,1% w/w	
SCXX...	AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
V2XX	MAGIC VAC CHAMPION / MASTER	Lead	7439-92-1	>0,1% w/w	
V272PK1	PERFETTA MV 230/50 (2)	Lead	7439-92-1	>0,1% w/w	
V4XX	MAGIC VAC GENIUS MV BASIC	Lead	7439-92-1	>0,1% w/w	
V7XX..	MAGIC VAC PROFESSIONAL JUMBO 30- JUMBO 30 PLUS/ JUMBO 30 EVO	Lead	7439-92-1	>0,1% w/w	
V9XX	MAGIC VAC LOGICA / PRIMIZIA/ ALICE/ VANTAGE	Lead	7439-92-1	>0,1% w/w	
VB11PK1	FUTURA MV BASIC 230/50 UK	Lead	7439-92-1	>0,1% w/w	
VB13PK1	TEKNA MV 230/50	Lead	7439-92-1	>0,1% w/w	
VB14PK1	MINIVAC BERK.	Lead	7439-92-1	>0,1% w/w	
VDXX..	MAGIC VAC MAXIMA 2/ AXOLUTE/BERK.	Lead	7439-92-1	>0,1% w/w	
VEXX..	MAGIC VAC ELITE 300 PLUS	Lead	7439-92-1	>0,1% w/w	
VF02PK1	EFFENNE AGILA 230/50	Lead	7439-92-1	>0,1% w/w	
VI02P00	VIBROFLOW C/MANOMETRO 230V50HZ	Lead	7439-92-1	>0,1% w/w	
VI06P00	PULMOWAVES 2 230V50HZ	Lead	7439-92-1	>0,1% w/w	
WIXX..	AR WI.NEB	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
E600E01	NE NAUTILUS II BASIC RF6 (VERS.A)	Lead	7439-92-1	>0,1% w/w	Buzzer ceramics
E600E02	NE NAUTILUS II BASIC (VERS.C)	Lead	7439-92-1	>0,1% w/w	
E600E03	NE NAUTILUS II BASIC (VERS.D)	Lead	7439-92-1	>0,1% w/w	
VI07P00	PULMOWAVES PRO LINE 230V 50HZ UK	Lead	7439-92-1	>0,1% w/w	
VI02P00	VIBROFLOW C/MANO 230V50HZ	Lead	7439-92-1	>0,1% w/w	
VI03P00	VIBROFLOW S/MANO 230V50HZ	Lead	7439-92-1	>0,1% w/w	
E601E00	NE NAUTILUS II BASIC	Lead	7439-92-1	>0,1% w/w	
E602E00	NE ULTRASUONI 309097 (6)	Lead	7439-92-1	>0,1% w/w	
E607E00	NE FASTNEB	Lead	7439-92-1	>0,1% w/w	
H610E53	NE HANDYNEB BASIC 230V50HZ NEW	Lead	7439-92-1	>0,1% w/w	
E215E21	NE EASYNEB III 15V 230V50HZ (8) NEW	Lead	7439-92-1	>0,1% w/w	
E300E22	NE EASYNEB VERSIONE 2003	Lead	7439-92-1	>0,1% w/w	
E300E21	NE ALISE0 PLUS 230V50HZ 2017 (6)	Lead	7439-92-1	>0,1% w/w	
E312E21	NE EASYNEB 3 15V 230V50HZ (8)	Lead	7439-92-1	>0,1% w/w	
MF02E00	NE SMARTY 2.0	Lead	7439-92-1	>0,1% w/w	
MF03E00	NE FIFTY (I)	Lead	7439-92-1	>0,1% w/w	
MF04E00	NE SMARTY 2.0 (EST)	Lead	7439-92-1	>0,1% w/w	
MF05E00	NE CLENNY A MICROFORI	Lead	7439-92-1	>0,1% w/w	
MF06E00	NE SMARTY 2.0 AUSTRALIA	Lead	7439-92-1	>0,1% w/w	
MF07E00	NE SMARTY 2.0 GR	Lead	7439-92-1	>0,1% w/w	
ACO655P	TESTINA DI NEBULIZZAZIONE (RIC)	Lead	7439-92-1	>0,1% w/w	
ACO656P	SERBATOIO FARMACO COMP.ESTRAIBILE	Lead	7439-92-1	>0,1% w/w	
MF3 ..EXX	AR LIGHTNEB	Lead	7439-92-1	>0,1% w/w	
ACO001C	TESTA DI NEBULIZZ. COMPL. LIGTHNEB	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
AP5XX...	AR AIR PRO F3000	Lead	7439-92-1	>0,1% w/w	Manometer/vuotometer connection (brass9
AR2XX..	AS ASPIRA GO 20 LT	Lead	7439-92-1	>0,1% w/w	
AR3XX..	AS ASPIRA GO 30 LT	Lead	7439-92-1	>0,1% w/w	
ASXX	AS ASPIRA PLUS	Lead	7439-92-1	>0,1% w/w	
PS11P00	AS PORT A SUCT.100/240V50/60 SWI EU	Lead	7439-92-1	>0,1% w/w	
PS30P00	AS PORT A SUCT.30L 100/240V50/60 EU	Lead	7439-92-1	>0,1% w/w	
P100P00	SUCT. PUMP II TRAC. 230V50HZ	Lead	7439-92-1	>0,1% w/w	
P400P00	TIRALATTE FLAEM 230V50HZ	Lead	7439-92-1	>0,1% w/w	
SPXX..	AS SUCTION PRO DP	Lead	7439-92-1	>0,1% w/w	
V7XX..	MAGIC VAC PROFESSIONAL JUMBO 30- JUMBO 30 PLUS/ JUMBO 30 EVO	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
CK01P00	AR CLENNY A KID	Lead	7439-92-1	>0,1% w/w	Motor spacer (brass)
VA30PK1	COLIBRI BABYFLAEM ABS 90040	Lead	7439-92-1	>0,1% w/w	
VB13PK1	TEKNA MV 230/50	Lead	7439-92-1	>0,1% w/w	
V051PK2	MINIMATIC MV 2010 WH. 230/50	Lead	7439-92-1	>0,1% w/w	
V212PK1	MAGIC VAC CHAMPION / MASTER	Lead	7439-92-1	>0,1% w/w	
V9XX	MAGIC VAC LOGICA / PRIMIZIA/ ALICE/ VANTAGE	Lead	7439-92-1	>0,1% w/w	
VD04PK1	AXOLUTE MV 230/50 (3) ACP19016	Lead	7439-92-1	>0,1% w/w	
VD07PK1	AXOLUTE MV 230/50 UK (3)	Lead	7439-92-1	>0,1% w/w	
VA52PK1	CHEFFY KIT MV PROF.230V50HZ	Lead	7439-92-1	>0,1% w/w	
VEXX..	MAGIC VAC ELITE 300 PLUS	Lead	7439-92-1	>0,1% w/w	
VF02PK1	AGILA 230/50	Lead	7439-92-1	>0,1% w/w	
ALXX...	AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
MIXX..	AEROSOL A PISTONE	Lead	7439-92-1	>0,1% w/w	
WIXX..	AR WI.NEB	Lead	7439-92-1	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
VEXX..	MAGIC VAC ELITE 300 PLUS	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	Sealing to seal the bags
VF02PK1	AGILA 230/50	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	
V9XX	MAGIC VAC LOGICA /PRIMIZIA/ALICE	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	
V4XX	MAGIC VAC GENIUS MV BASIC	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	
VB11PK1	FUTURA MV BASIC 230/50 UK	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	
VB13PK1	TEKNA MV 230/50	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	
VB14PK1	MINIVAC BERK.	Octamethylcyclotetrasiloxane	556-67-2	>0,1% w/w	

Article	Article Description	Name of substance in the Candidate List	CAS	Concentration	Localisation of substance
AR2XX..	AS ASPIRA GO 20 LT	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, vase holder
AR3XX..	AS ASPIRA GO 30 LT	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, vase holder
AR4XX..	AS ASPIRA GO 40 LT	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, vase holder, pedal
ASXX	AS ASPIRA PLUS	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, vase holder
Y301XX	AEROSOL A PISTONE NEBULFLAEM	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body
DRXX...	DOCCE NASALI MOBILE, DOCCE NASALI SPRINT	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body
V001P02	ELITE DN	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, cutter body
V272P00	NEW CHAMPION PREMIUM 230/50 P0116ED	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, cutter body
V272PK1	MAGIC VA PERFETTA MV 230/50 (2)	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, cutter body
V401P01	GENIUS DN 115/60 UL	Triphenyl phosphate TPP	115-86-6	0,1%-2,5% w/w	External body, cutter body
V961PK2	ALICE KIT 100V50-60HZ V952SA (4)	Triphenyl phosphate	Triphenyl phosphate	0,1%-2,5% w/w	External body, cutter body

Recommendations for safe use, as required by art. 33, par. 1 of Reg. (EC) 1907/2006 (REACH) and subsequent amendments:

In Brass motor eccentric joint, spacers and pins, Lead is an alloying element (therefore strongly alloyed). Likewise, the Lead compounds in the ceramics are immersed and stable in the ceramic matrix: therefore exposure to Lead or the listed Lead compounds is not expected.

If the products have to be disposed of, it is only recommended to manage the Flaem products as WEEE.

Regarding the presence of N-methyl pyrrolidone present in the motor windings and octamethylcyclotetrasiloxane in the gaskets, triphenyl phosphate in plastic bodies, it is recommended to:

- do not burn the product, dispose of it as WEEE
- use the product in accordance to the rating data on the device

In conclusion: under normal and reasonably foreseeable conditions of use, exposure to the Candidate List substances present in the listed articles is not foreseen.

However, in case of maintenance, repair and disposal operations, avoid direct contact with the components affected by the presence of Candidate List substances.

After use, it is recommended to follow normal hygiene practices (wash hands after handling, do not eat while wearing gloves, etc.).

For disposal, contact an authorized waste management company according to national and local regulations. Do not disperse in the environment.



FLAEM NUOVA SPA
Via Colli Storici, 221/223/225,
25015 Desenzano del Garda (BS), Italy
+39 030 9910168
www.gruppoflaem.it

MAIL info@gruppoflaem.it
PEC flaemnuova@legalmail.it
C.F. 01150910170
P.IVA 00605150986
C.U. A4707H7

San Martino della Battaglia, Desenzano (BS), Italy 03/06/2025

In Faith,

The General Manager

Riccardo Abate

Note: the above information and our technical advice are given in good faith but without any warranty. Our advice does not release you from the obligation to check its validity and to test our products as to the suitability for the intended processes, uses and compliance to current legislation.