

B. Braun Avitum Italy S.p.A.

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**Reporting requirement according to paragraph 33 of the REACH regulation
(EC) No. 1907/2006)**

December 14, 2020

Dear Sir or Madam,

As you know, with the CE-labelling and with the declaration of conformity of our medical devices we confirm that the respective products are in compliance with the "essential requirements" of the European Medical Device Directive (93/42/EEC) and the German Act on Medical Devices or already the "essential safety and performance requirements" of the European Medical Device Regulation (EU) 2017/745, which is being implemented for our products step by step till May 2024.

This includes that our products are designed and manufactured in a way that, when used under the conditions and for the purpose intended, they will not compromise the clinical condition or the safety of patients nor the safety and health of users or third parties. Respective assessments are carried out a.o. in relation with the application of a Risk Management System implemented according to ISO 14971 for medical devices.

With implementation of the European Chemical Regulation 'REACH' (Registration, Evaluation and Authorisation of Chemicals) we have to inform which products include a substance named in the so called list of candidates in a concentration of more than 0.1 mass percentage. This list was first published on the website of the European Chemicals Agency (ECHA) on October 28, 2008 and has been updated continuously.

Concerning substances published so far in the list of candidates,

- DEHP (Bis(2-ethylhexyl) phthalate, CAS No 117-81-7) and
 - DOTE (2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8oxa-3,5-dithia-4-stannatetradecanoate, CAS No 15571-58-1)
- are present in some of our products in relevant concentrations of more than 0.1 mass percent. These products are listed in the annexes to this letter.

The affected products of the manufacturer B. Braun Avitum Italy S.p.A., which contain DEHP by more than 0.1 mass percent, are labeled as follows, based on Regulations (EC) No. 1272/2008 (CLP Regulation) and (EC) No. 1907/2006 (REACH Regulation):

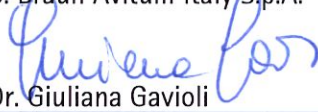


With this information letter we comply with the obligation to provide information according to article 33 §1 of the REACH Regulation. This letter will be updated if a substance relevant to our products is added to the list of candidates. Until then this letter retains its validity.

For further questions please do not hesitate to contact us.

Kind regards

B. Braun Avitum Italy S.p.A.



Dr. Giuliana Gavioli
QM / RA Director



Chiara Bergamini
RA Manager

Annex 1: List of DEHP-containing products
Annex 2: List of DOTE-containing products

Annex 1 to the letter "Reporting requirement according to Article 33 of the REACH Regulation (EC) No. 1907/2006"

List of DEHP-containing products

The following B. Braun Avitum Italy S.p.A. products contain more than 0.1 mass percent of DEHP (Bis(2-ethylhexyl) phthalate, CAS No 117-81-7):

Article	Article description
2112016	Solu-care
2112125	Evarex® Secondary Module Circuit for Caretronic®
2112227	Evarex® Bag with Filling Set
2112228	Evarex® Bag with Filling Set
2112229	Evarex® Bag with Filling Set
2112230	Evarex® Bag with Filling Set
2112231	Evarex® Bag with Filling Set
2112250	Evarex® Primary Module Circuit for Caretronic®
2112268	ECOSPIKE N°1
2112269	ECOCLICK N°1
2112270	ECOSPIKE N°2
2112271	ECOCLICK N°2
2112272	ECOCLICK N°4
2112274	Extension Set for Ecospike / Ecoclick® (60cm)
2112277	Ecoclick® Nr. 1 Arthroscopy
2112278	Ecospike® Nr. 2 Arthroscopy
2112279	Ecoclick® Nr. 2 Arthroscopy
2124602	PAEDIFIX N
7210064	Solu-care
7210110	Solu-care

Annex 2 to the letter "Reporting requirement according to Article 33 of the REACH Regulation (EC) No. 1907/2006"

List of DOTE-containing products

The following B. Braun Avitum Italy S.p.A. products contain more than 0.1 mass percent of DOTE (2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate, CAS number 15571-58-1):

Article	Article description
2112010	EVA BAG EVAREX 3/3 WITH 50µM FILTER
2112067	EVA BAG EVAREX 1/3 WITH 50µM FILTER
2112068	EVA BAG EVAREX 2/3 WITH 50µM FILTER
2112096	EVA BAG EVAREX 0.5/3 WITH 50µM FILTER
2112103	1WAY FILLING SET
2112125	SET FOR CARETRONIC SECONDARY MODULE
2112128	EVA/BARRIER BAG EVAREX 3/6 W/ 50µM F.
2112312	INFUSION KIT VISUDYNE
2112321	EVA BAG NUTRIMIX 0.5/3 WITH 50µM FILTER
2112323	EVA BAG NUTRIMIX 3/3 WITH 50µM FILTER
2112335	EVA/BARRIER BAG EVAREX 5/6 W/ 50µM F.
2112413	EVAREX/BARRIER 4/6 BAG WITH 50µM FILTER
2112498	TRANSFER SET FOR MICRO-COMPOUNDER Nr. 1
2112499	TRANSFER SET FOR MICRO-COMPOUNDER Nr. 2
4608670	STRAW FOR EXADORAL LENGTH 100MM
4608671	STRAW FOR EXADORAL LENGTH 170MM
4616006	STRAW FOR OMNIFIX LENGTH 100MM
4616007	STRAW FOR OMNIFIX LENGTH 170MM
4616009	STRAW FOR ENTERAL SYRINGE W/ENFIT 100MM
4616013	STRAW FOR ENTERAL SYRINGE W/ENFIT 170MM
7210064	SOLU/CARE EXTENSION MLL/FLL
7210110	SOLU-CARE 1X2X2000
8721688	ENTEROPORT PLUS SET FL
8721726	ENTEROPORT PLUS SET 500
8721734	ENTEROPORT PLUS SET 1000
8721735	ENTEROPORT PLUS SET 1000 SAFETY
8721736	ENTEROPORT PLUS ENFIT SET 1000ML-TRANSIT
8721737	ENTEROPORT PLUS SET 1000 ENFIT
8721742	ENTEROPORT PLUS SET 2500
8721742	ENTEROPORT PLUS SET 2500
8721744	ENTEROPORT PLUS SET UNIV.ADAPTER
8721745	ENTEROPORT PLUS SET UNIV. ADAPTER SAFETY
8721746	ENTEROPORT PLUS ENFIT SET W/UNIV ADAP-TR
8721747	ENTEROPORT PLUS UNIVERSAL ADAPTER ENFIT
8721748	ENTEROPORT PLUS ENFIT SET W/ENP.SPIKE-TR
8721749	ENTEROPORT PLUS ENFIT SET W/ENP.SPIKE

8721750	ENTEROPORT PLUS SET MULTISPIKE
9240621	NUTRIFIX UNIVERSAL ADAPTER - HF
9240622	NUTRIFIX UNIVERSAL ADAPTER SAFETY
9240623	NUTRIFIX ENFIT SET W/UNIV.ADAP.-TRANSIT
9240624	NUTRIFIX UNIVERSAL ADAPTER ENFIT
9240625	NUTRIFIX ENFIT SET W/ENP.SPIKE - TRANSIT
9240626	NUTRIFIX ENFIT SET W/ENP.SPIKE
9240632	NUTRIFIX MULTISPIKE - HF
9240669	NUTRIFIX FL - HF
9240677	NUTRIFIX 1000 ML-HF
9240678	NUTRIFIX 1000 ML SAFETY
9240679	NUTRIFIX ENFIT SET 1000ML - TRANSITION
9240680	NUTRIFIX SET 1000 ML ENFIT
9240685	NUTRIFIX 2500 ML-HF
9246508	NUTRITUB PAED ENFIT CH5, 50CM
9246511	NUTRITUB PAED ENFIT CH6, 60CM
9246512	NUTRITUB GASTRAL ENFIT CH10,110CM W/M
9246513	NUTRITUB GASTRAL ENFIT CH14,110CM W/M
9246514	NUTRITUB GASTRAL ENFIT CH14,110CM W/O M.
9246515	NUTRITUB GASTRAL ENFIT CH16,110CM W/M
9246516	NUTRITUB GASTRAL ENFIT CH16,110CM W/O M.
9246518	NUTRITUB GASTRAL ENFIT CH18,110CM W/M
9246519	NUTRITUB GASTRAL ENFIT CH18,110CM W/O M.
9246535	NUTRITUB GASTRAL ENFIT CH8,80CM W/O MAN.
9246543	NUTRITUB GASTRAL ENFIT CH12,110CM W/M
9246578	NUTRITUB INTESTINAL ENFIT CH8,125CM
9246586	NUTRITUB INTESTINAL ENFIT CH12,125CM

