

Dear sir,

I would like to submit to your verification the following consideration performed in the last month.

Diffuplast started the collaboration with SterilMilano in 2010. Diffuplast was one of the first customers of Steril Milano. In that time, Steril Milano was founded by 2 founders. After some years, remained only Carlo Salvetti who put in place the fraud.

Our initial validation performed in 2010 in Monza site were prepared by the other founder as technical manager and approved by microbiological laboratory person as quality manager. Both of them are not involved in the fraud. From Diffuplast side, the validation was approved by quality manager of Diffuplast and by an external expert as validation manger.

Diffuplast considers this validation valid since it can be confirmed by following several assumptions.

- The analysis of BI was not performed by Steril Milano but performed by an external laboratory during the validation process.
- Diffuplast is performing a validation in Steril Verona. Steril Verona has the same equipment and same cycle of Steril Milano as stated in the attachment (razionale equivalenza). It is in Italian but from the tables it is evident the equivalency (if you need, we will provide you also the translation).
- Diffuplast has already performed a half cycle and the bags used for validation were found sterile (see Sterility test in attachment). The half cycle consists in the same cycle of routine but the contact time with Eo sterilization gas is half. It is a *safety factor*.
- Bags used for the sterility test were assembled to be worse than the devices in the market.



*Note: It is a 5000 ml bag with a tube long 2 mt with internal diameter of 3 mm with a spike with a vented cap in the end. The penetration of the sterilizing agent and the humidity during sterilization is very critical in the sample used for validation.*

Bags in the market are extremely less complex than the one used for validation. Bags in the market are without set or if bags have a set, it is 3 way and not 1 way and it has a shorter length tube (1 mt instead of 2 mt). Diffuplast considers it as a *safety factor*.

- For the validations in Steril Verona and Steril Milano, the BI Bacillus atrophaeus (var niger) is used. The natural bioburden of Diffuplast products shows much less population and less resistance versus the Biological indicators. The bioburden values for entire product range of Diffuplast products are extremely low. Media of values of 2020: 1,82 CFU/device and media of values from 2018 to 2021 is 1,4 CFU/device. This can be considered as a *safety factor* since the sterilization process was set up on worst case (bioindicator) instead on the natural bioburden of Diffuplast products (extremely less than bioindicators).

- Diffuplast is aware that several compounding centres are performing sterility tests during their routine controls. These tests can be from three in each day to one every week. From the statistical point of view of 10 years data, if the initial validation was compromised, some devices should be found not sterile. Even if some customers are not performing sterility tests during their routine activities, all devices in all markets were sterilized in the same sterilization cycle of devices in countries where they perform sterility test as routine activity.

In the report Steril Milano Fraud Investigation Interim report V6 of 19/4/2021 as a conclusion it is stated that the logical chain of OQ → PQ/product validations → routine treatment is 'broken' but Diffuplast entered in the detail of document taking in consideration the analysis and the evidence already performed/provided by Steril Milano.

- The validation for Diffuplast products can be considered valid according to above statement and evidence.
- The OQ and equivalency is conforming even if the years the OQs were performed 1-2 months later.
- The calibration of probes for routine treatment were controlled. Probe calibration is conforming. It means that the raw data graphs can be used as trustworthy.

In the specific case of Diffuplast products, the logical chain OQ → PQ/product validations → routine treatment is **not** considered 'broken'.

About BI management: the position of BI was performed by Diffuplast before sending pallets to Steril Milano therefore the number of placed BI and the positioning was not altered by Steril Milano. For 2021 cycles, Steril Milano has not the evidence of positive BI (see attachment Diffuplast BI).

Based on this information, Diffuplast performed the analysis of raw data (graphs and reports) also with the collaboration of the same external sterilization expert who signed the initial validation.

For the evaluation, Diffuplast followed the precautionary measure. If data was contradictory and not reliable, Diffuplast decided to recall the batch as a *safety factor*.

I can make one example: in the report the EO gas introduced in the sterilization chamber was - 9000 kg. This data does not make sense. Probably the problem was only an error in the scale (balance) since the pressure vacuum were conform and the Eo gas introduction is made when the pressure level goes up and the batch number of cylinders containing Eo gas were inserted in report. Even if the process of gas introduction and the Eo weight most probably were conforming, Diffuplast prefers to place the batch among the recalled batches.

Diffuplast identified all the compromised cycles with non conformities or no data which could put product sterility at risk and Diffuplast initiated the recall in the market with FSN of 20 April 2021.

As a conclusion, since for Diffuplast products the logical chain of OQ → PQ/product validations → routine treatment is not 'broken', the routine treatment can be considered conforming and yielded sterility. Even if Steril Milano is not entitled or able to conclude whether product sterility has been achieved, Diffuplast as manufacturer provided a sequence of evidences.

According to the report Steril Milano Fraud Investigation Interim report V6 of 19/4/2021:

- Steril Milano is not able to verify and confirm or quantify isolated fraudulation steps and relate them to specific batches or clients is only for Eo biological indicators. Diffuplast didn't take in account the bioindicator management in the analysis of data. Diffuplast focuses on the graph analysis. Only evidence is that management of BI for Diffuplast product were conform in 2021.
- Steril Milano will not be able to determine specifically for single validations which type of falsification occurred as no record of these wrongdoings exist. Diffuplast validation can be consider valid since were not performed by mr. Carlo Salvetti and the evidence that the Steril Milano sterilization cycle is conform for worst case Diffuplast product was provided.
- The logical chain of qualification steps, process/product validations and routine treatment is not 'broken' since the evidence/analysis or OQ and calibrations were provided by Steril Milano.

Diffuplast considers that all the other batches not recalled yet and not part of FSN of 20 April 2021 were submitted to a conform sterilization cycle considering the above assumption also because some safety factors were considered in our analysis.

Diffuplast appreciates the support of all Competent Authorities in this difficult issue.

17/5/2021

Veronica Vignati  
QA  
Diffuplast srl

**Field Safety Notice**  
**Ref: SRC**



Diffuplast S.r.L.  
Via Piave 48,  
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Italia

*April 20, 2021*

Dear customer,

Diffuplast is conducting a Field Safety Corrective Action for:

- Parenteral nutrition bags (ExactaMix eva, Exacta Mix multilayer, DiMix eva, Di Mix multilayer, Nutri-bag eva, Nutri-bag multicapa, KabiHelp uno, KabiHelp advance plus, KabiHelp duo)
- Enteral nutrition bags (Di Eto, Nutri-bag enteral)
- Connection sets
- Filling sets
- Transfer sets
- Preparation sets
- Extension sets

See Annex 1 for full lists of all impacted products (REFs) and batches (LOTs).

Diffuplast has been informed by its EO sterilisation supplier that a member of the company's staff has intentionally falsified records relating to sterilisation processes carried out from 2010 onwards. The EO sterilisation supplier has provided raw data for sterilisation cycles carried out in 2018, 2019, 2020 and 2021, downloaded by an external independent company from the supplier's SCADA system. No data has been received for sterilisations carried out in previous years. Diffuplast conducted an analysis of the raw data, but some information is still missing or incongruent and not completely reliable. Based on our post market surveillance, no incident has occurred and no notification has been received about infection since 2010.

For the batches listed in Annex 1:

- You can continue to use the devices at risk, until an alternative product can be supplied.
- If bags are already with patients, they can be used.
- Continue on-site device inspection as per your routine sterility assurance testing. Additional testing is not required.

If a validated sterility test has failed, then:

- Do not use the devices from that batch on patients;
- Provide the batch number of the bag tested and the results of the test with a detailed explanation of the method used to carry out the test;
- Provide 12 months of retrospective sterility testing data for comparison. Diffuplast will review your data and take appropriate action.

If you have already used the above-stated batches, monitor patients closely for evidence of infection and ensure cases of suspected TPN-associated infection are reported to the national Competent Authority. Raw data analysis and congruence verification with the support of the EO sterilisation site and our post-market surveillance is ongoing. Diffuplast will issue further advice and information as appropriate.

If you have enough alternative products and you would like to return the affected devices referred to above, please fill the form provided in Annex 2.

Please, share this notice with other organisations that may be impacted by the details in this FSN.

Diffuplast is working actively to qualify alternative sterilisation facilities for the devices in question.

Your assistance is sincerely appreciated. Diffuplast sincerely apologises for any inconvenience this FSN may cause to your organisation and your staff.

*Giuseppe Vignati*  
Diffuplast S.r.l.

## ANNEX 1 – AFFECTED BATCHES

### Parenteral bags

REF.	NAME	LOT	STERILISATION BATCH
8000003	Di Mix eva	H090	18072011
8000003	Di Mix eva	L153	20101311
8000004	Di Mix eva	H090	18072011
8000005	Di Mix eva	H090	18072011
8000006	Di Mix eva	H090	18072011
10065.0HC	Di Mix eva	H005	18011611
10065.0HC	Di Mix eva	H061	18051811
10065.0HC	Di Mix eva	H081	18071011
100650B5	Di Mix eva	I116	19080211
10065-EVA	Di Mix eva	H050	18050411
10133.0HC	Di Mix eva	H005	18011611
10133.0HC	Di Mix eva	H061	18051811
10133.0HC	Di Mix eva	H081	18071011
10133/1	Di Mix eva	H050	18050411
10133/1	Di Mix eva	H098	18080311
10133/1	Di Mix eva	H123	18100511
10133/1	Di Mix eva	L189	21011211
101330B5	Di Mix eva	I116	19080211
101330B5	Di Mix eva	L193MN	21010812
101330B5	Di Mix eva	L197MN	21011211
1024.0DE	Di Mix eva	H005	18011611
1024.0DE	Di Mix eva	H081	18071311
1024.0DE	Di Mix eva	H101	18080311
10240B5	Di Mix eva	L146MR	20101311
1024-A/1	Di Mix eva	H050	18050411
1024-A/1	Di Mix eva	H098	18080311
1024-A/1	Di Mix eva	H123	18100511
1024-A/1	Di Mix eva	L147	20101311
1035.3HC	Di Mix eva	H005	18011611
1035.3HC	Di Mix eva	H081	18071311
10350B5	Di Mix eva	I096	19070211
1301.0	Di Mix eva	H005	18011611
1301.0	Di Mix eva	H046	18042011
1302.0S	Di Mix eva	H100	18080311
1302.3	Di Mix eva	H005	18011611
1302.3	Di Mix eva	H046	18042011
1305.3	Di Mix eva	H005	18011611
1310.0	Di Mix eva	H005	18011611
1320.3	Di Mix eva	H081	18071311
1320.3	Di Mix eva	H101	18080311
1320.3	Di Mix eva	I160TE	19102312
1320.3IS	Di Mix eva	H101	18080311
1320.3IS	Di Mix eva	L148AE	20102311
1320-A	Di Mix eva	H098	18080311
1330.3	Di Mix eva	H005	18011611

REF.	NAME	LOT	STERILISATION BATCH
1330.3	Di Mix eva	H046	18041711
1330.3	Di Mix eva	H061	18051811
1330.3	Di Mix eva	H081	18071011
1330.3	Di Mix eva	H081	18071311
1330.3	Di Mix eva	H145	18111311
1330.3	Di Mix eva	I127TF	19091013
1330.3	Di Mix eva	I138TF	19100411
1330.3	Di Mix eva	I160TF	19102312
1330.3	Di Mix eva	I176	19111416
1330.3	Di Mix eva	M003TF	21011514
1330.3D	Di Mix eva	L195	21011211
1330.3IS	Di Mix eva	H005	18011611
1330.3IS	Di Mix eva	H046	18042011
1330.3IS	Di Mix eva	I138AF	19100411
1330.3IS	Di Mix eva	M003AF	21011514
1330A	Di Mix eva	H123	18100511
1335.3	Di Mix eva	H046	18041711
1335.3	Di Mix eva	I138TG	19100411
1335.3IS	Di Mix eva	H046	18042011
1335.3IS	Di Mix eva	I138AG	19100411
20065.0HC	Di Mix eva	H061	18051811
20065.0HC	Di Mix eva	H081	18071011
20133.0HC	Di Mix eva	H061	18051811
20133.0HC	Di Mix eva	H081	18071011
2024.0DE	Di Mix eva	H081	18071311
2330.3IS	Di Mix eva	M003XF	21011514
82.1302.0C	Di Mix eva	I120	19090215
82.1305.0	Di Mix eva	I120	19090215
82.1305.0C	Di Mix eva	I120	19090215
82.1310.0C	Di Mix eva	I120	19090215
82.1310.0C	Di Mix eva	L154	20102311
82.1320.3C	Di Mix eva	H060	18051811
82.1320.3C	Di Mix eva	I009	19011811-1
82.1330.0	Di Mix eva	L154	20102311
82.1330.0C	Di Mix eva	L154	20102311
82.1330.0C	Di Mix eva	L198	21011211
82.1350.3	Di Mix eva	H039	18040411
82.1350.3	Di Mix eva	L154	20102311
1420.3	Di Mix multilayer	H081	18071311
1440.3	Di Mix multilayer	H005	18011611
82.1402.0C	Di Mix multilayer	H027	18022711
82.1402.0C/5	Di Mix multilayer	H027	18022711
82.1405.0C	Di Mix multilayer	H118	18092111
82.1410.0C	Di Mix multilayer	H118	18092111
82.1430.6	Di Mix multilayer	H060	18051811
82.1430.6	Di Mix multilayer	I171	19103113
82.1430.6	Di Mix multilayer	L154	20102311
82.1430.6	Di Mix multilayer	L198	21011211

REF.	NAME	LOT	STERILISATION BATCH
T99000	Di Mix multilayer	G162PF	18010811
T99000	Di Mix multilayer	G164PF	18010811
T99000	Di Mix multilayer	G164PF	18010911
T99000	Di Mix multilayer	H035PF	18030911
T99000	Di Mix multilayer	H044PF	18041011
T99000	Di Mix multilayer	H048PF	18042411
T99000	Di Mix multilayer	H054PF	18042711
T99000	Di Mix multilayer	H085PF	18070611
T99000	Di Mix multilayer	H105PF	18082811
T99000	Di Mix multilayer	H105PF	18083113
T99000	Di Mix multilayer	H107PF	18090414
T99000	Di Mix multilayer	H112PF	18091111
T99000	Di Mix multilayer	H119PF	18092111
T99000	Di Mix multilayer	I074PF	19052111
T99000	Di Mix multilayer	I114PF	19073011_1
T99000	Di Mix multilayer	I118PF	19080211
T99000	Di Mix multilayer	I118PF	19080611
T99000	Di Mix multilayer	I128PF	19091913
T99000	Di Mix multilayer	I135PF	19091913
T99000	Di Mix multilayer	I135PF	19092411
T99000	Di Mix multilayer	I142PF	19092613
T99000	Di Mix multilayer	I153PF	19101111
T99000	Di Mix multilayer	I153PF	19101511
T99000	Di Mix multilayer	I159PF	19102312
T99000	Di Mix multilayer	I166PF	19103113
T99000	Di Mix multilayer	L156PF	20102311
T99000	Di Mix multilayer	L192PF	21010814
T99000	Di Mix multilayer	M005PF	21012211
T99021	Di Mix multilayer	H044QC	18041311
T99021	Di Mix multilayer	I153QC	19101511
T99022	Di Mix multilayer	H044QD	18041311
T99023	Di Mix multilayer	H094QE	18072711
T99023	Di Mix multilayer	I108QE	19072311
T99023	Di Mix multilayer	I169QE	19111416
T99023	Di Mix multilayer	L142QE	20101311
T99025	Di Mix multilayer	I128PG	19091013
T99025	Di Mix multilayer	I128PG	19091913
T99025	Di Mix multilayer	I159PG	19102312
T99025	Di Mix multilayer	L192PG	21010812
T99026	Di Mix multilayer	I128PH	19091913
T99026	Di Mix multilayer	I159PH	19102312
T99026	Di Mix multilayer	L192PH	21010812
E1301OLPF	Exacta Mix eva	I154CA	19101811
E1302OLPF	Exacta Mix eva	H032CB	18030911
E1302OLPF	Exacta Mix eva	H043CB	18040411
E1302OLPF	Exacta Mix eva	H099CB	18080311
E1302OLPF	Exacta Mix eva	H132CB	18102613
E1302OLPF	Exacta Mix eva	L176CB	20120111

REF.	NAME	LOT	STERILISATION BATCH
E1302OLPF5	Exacta Mix eva	L194DB	21011514
E13050LPF	Exacta Mix eva	H032CC	18030911
E1305OLPF	Exacta Mix eva	H047CC	18041311
E1305OLPF	Exacta Mix eva	H082CC	18062911
E1305OLPF	Exacta Mix eva	I113CC	19080211
E1305OLPF5	Exacta Mix eva	I172DC	19111416
E1310OLPF	Exacta Mix eva	H053CD	18050211
E1310OLPF	Exacta Mix eva	H117CD	18092111
E1310OLPF	Exacta Mix eva	H132CD	18102613
E1310OLPF	Exacta Mix eva	I119CD	19080611
E1310OLPF	Exacta Mix eva	I154CD	19101511
E1310OLPF	Exacta Mix eva	L149CD	20101311
E1320OLPF	Exacta Mix eva	H053CE	18050211
E1320OLPF	Exacta Mix eva	H053CE	18050411
E1320OLPF	Exacta Mix eva	H084CE	18071011
E1320OLPF	Exacta Mix eva	H093CE	18072411
E1320OLPF	Exacta Mix eva	H143CE	18111311
E1320OLPF	Exacta Mix eva	I007CE	19011811-1
E1320OLPF	Exacta Mix eva	I156CE	19101511
E1330OLPF	Exacta Mix eva	H057CF	18051511
E1330OLPF	Exacta Mix eva	H143CF	18111311
E1330OLPF	Exacta Mix eva	I143CF	19100111
E1330OLPF	Exacta Mix eva	L149CF	20101311
E1330OLPF	Exacta Mix eva	L194CF	21011514
E1340OLPF	Exacta Mix eva	H143CG	18111311
E1401OD	Exacta Mix multilayer	H126FA	18100911
E1401OD	Exacta Mix multilayer	I093FA	19070211
E1401OD	Exacta Mix multilayer	I151FA	19101111
E1401OD	Exacta Mix multilayer	L149FA	20101311
E1401OD5	Exacta Mix multilayer	H124NA	18100911
E1401OD5	Exacta Mix multilayer	I154NA	19101811
E1401OD5	Exacta Mix multilayer	L149NA	20101311
E1402OD	Exacta Mix multilayer	H132FB	18102613
E1402OD	Exacta Mix multilayer	I113FB	19080211
E1402OD	Exacta Mix multilayer	M002FB	21011514
E1402OD	Exacta Mix multilayer	M002FB	21012114
E1402OD5	Exacta Mix multilayer	I093NB	19070211
E1405OD	Exacta Mix multilayer	H047FC	18041311
E1405OD	Exacta Mix multilayer	H082FC	18062911
E1405OD	Exacta Mix multilayer	I154FC	19101511
E1405OD5	Exacta Mix multilayer	I053NC	19040911
E1410OD	Exacta Mix multilayer	H053FD	18050211
E1410OD	Exacta Mix multilayer	H096FD	18073111
E1410OD	Exacta Mix multilayer	H111FD	18091111
E1410OD	Exacta Mix multilayer	I113FD	19073011_1
E1410OD	Exacta Mix multilayer	I113FD	19080211
E1410OD	Exacta Mix multilayer	I126FD	19091013
E1410OD	Exacta Mix multilayer	L157FD	20102311



REF.	NAME	LOT	STERILISATION BATCH
E1410OD5	Exacta Mix multilayer	H053ND	18042711
E1410OD5	Exacta Mix multilayer	L157ND	20102311
E1420OD	Exacta Mix multilayer	H043FE	18040411
E1420OD	Exacta Mix multilayer	H053FE	18050211
E1420OD	Exacta Mix multilayer	H055FE	18050411
E1420OD	Exacta Mix multilayer	H055FE	18050811
E1420OD	Exacta Mix multilayer	H057FE	18050811
E1420OD	Exacta Mix multilayer	H059FE	18051511
E1420OD	Exacta Mix multilayer	H079FE	18062911
E1420OD	Exacta Mix multilayer	H084FE	18071011
E1420OD	Exacta Mix multilayer	H086FE	18071011
E1420OD	Exacta Mix multilayer	H088FE	18071711
E1420OD	Exacta Mix multilayer	H091FE	18072011
E1420OD	Exacta Mix multilayer	H093FE	18072411
E1420OD	Exacta Mix multilayer	H096FE	18073111
E1420OD	Exacta Mix multilayer	H096FE	18080311
E1420OD	Exacta Mix multilayer	H102FE	18080711
E1420OD	Exacta Mix multilayer	H104FE	18082212
E1420OD	Exacta Mix multilayer	H122FE	18100211
E1420OD	Exacta Mix multilayer	H122FE	18100911
E1420OD	Exacta Mix multilayer	H124FE	18100911
E1420OD	Exacta Mix multilayer	H126FE	18100911
E1420OD	Exacta Mix multilayer	H141FE	18111311
E1420OD	Exacta Mix multilayer	H143FE	18111311
E1420OD	Exacta Mix multilayer	I053FE	19040911
E1420OD	Exacta Mix multilayer	I107FE	19072311
E1420OD	Exacta Mix multilayer	I109FE	19072311
E1420OD	Exacta Mix multilayer	I113FE	19073011_1
E1420OD	Exacta Mix multilayer	I124FE	19090215
E1420OD	Exacta Mix multilayer	I130FE	19091013
E1420OD	Exacta Mix multilayer	I132FE	19091013
E1420OD	Exacta Mix multilayer	I143FE	19100111
E1420OD	Exacta Mix multilayer	I145FE	19100411
E1420OD	Exacta Mix multilayer	I147FE	19100411
E1420OD	Exacta Mix multilayer	I172FE	19111416
E1420OD	Exacta Mix multilayer	L157FE	20102311
E1420OD	Exacta Mix multilayer	L178FE	20120111
E1420OD	Exacta Mix multilayer	L180FE	20120111
E1420OD	Exacta Mix multilayer	L182FE	20120111
E1420OD	Exacta Mix multilayer	M006FE	21012211
E1420OD5	Exacta Mix multilayer	H059NE	18051511
E1420OD5	Exacta Mix multilayer	H099NE	18080311
E1420OD5	Exacta Mix multilayer	I154NE	19101811
E1430OD	Exacta Mix multilayer	G163FF	18010911
E1430OD	Exacta Mix multilayer	H004FF	18011611
E1430OD	Exacta Mix multilayer	H045FF	18041011
E1430OD	Exacta Mix multilayer	H047FF	18041011
E1430OD	Exacta Mix multilayer	H049FF	18041311

REF.	NAME	LOT	STERILISATION BATCH
E1430OD	Exacta Mix multilayer	H049FF	18041711
E1430OD	Exacta Mix multilayer	H051FF	18041711
E1430OD	Exacta Mix multilayer	H051FF	18042011
E1430OD	Exacta Mix multilayer	H059FF	18051811
E1430OD	Exacta Mix multilayer	H082FF	18062911
E1430OD	Exacta Mix multilayer	H104FF	18082212
E1430OD	Exacta Mix multilayer	H108FF	18082811
E1430OD	Exacta Mix multilayer	H111FF	18091111
E1430OD	Exacta Mix multilayer	H132FF	18102613
E1430OD	Exacta Mix multilayer	I005FF	19011511
E1430OD	Exacta Mix multilayer	I007FF	19011811-1
E1430OD	Exacta Mix multilayer	I053FF	19040911
E1430OD	Exacta Mix multilayer	I093FF	19070211
E1430OD	Exacta Mix multilayer	I113FF	19073011_1
E1430OD	Exacta Mix multilayer	I113FF	19080211
E1430OD	Exacta Mix multilayer	I115FF	19080611
E1430OD	Exacta Mix multilayer	I124FF	19090215
E1430OD	Exacta Mix multilayer	I137FF	19092411
E1430OD	Exacta Mix multilayer	I151FF	19101111
E1430OD	Exacta Mix multilayer	I163FF	19103113
E1430OD	Exacta Mix multilayer	L194FF	21010814
E1430OD	Exacta Mix multilayer	L194FF	21011211
E1430OD5	Exacta Mix multilayer	H004NF	18011611
E1430OD5	Exacta Mix multilayer	H028NF	18022711
E1430OD5	Exacta Mix multilayer	H051NF	18042011
E1430OD5	Exacta Mix multilayer	H088NF	18071711
E1430OD5	Exacta Mix multilayer	H099NF	18080311
E1430OD5	Exacta Mix multilayer	H122NF	18100211
E1430OD5	Exacta Mix multilayer	H122NF	18100511
E1430OD5	Exacta Mix multilayer	I005NF	19011511
E1430OD5	Exacta Mix multilayer	I005NF	19011811-1
E1430OD5	Exacta Mix multilayer	I073NF	19052111
E1430OD5	Exacta Mix multilayer	I113NF	19080211
E1430OD5	Exacta Mix multilayer	I175NF	19112211
E1430OD5	Exacta Mix multilayer	L194NF	21011211
E1430OD5	Exacta Mix multilayer	L199NF	21011514
E1440OD	Exacta Mix multilayer	H057FG	18050811
E1440OD	Exacta Mix multilayer	H057FG	18051511
E1440OD	Exacta Mix multilayer	H059FG	18051811
E1440OD	Exacta Mix multilayer	H093FG	18072411
E1440OD	Exacta Mix multilayer	H102FG	18080711
E1440OD	Exacta Mix multilayer	I005FG	19011511
E1440OD	Exacta Mix multilayer	I005FG	19011811-1
E1440OD	Exacta Mix multilayer	I122FG	19090215
E1440OD	Exacta Mix multilayer	I177FG	19112211
E1440OD5	Exacta Mix multilayer	H059NG	18051511
E1440OD5	Exacta Mix multilayer	H088NG	18071711
E1440OD5	Exacta Mix multilayer	H099NG	18080311

REF.	NAME	LOT	STERILISATION BATCH
E1450OD	Exacta Mix multilayer	H086FH	18071011
E1450OD	Exacta Mix multilayer	I005FH	19011511
E1450OD	Exacta Mix multilayer	I070FH	19052111
28014021	Kabi Help advance plus	L196SB	21011211
28014101	Kabi Help advance plus	I139SD	19092613
28014201	Kabi Help advance plus	H087SE	18071011
28014201	Kabi Help advance plus	H087SE	18071311
28014201	Kabi Help advance plus	H095SE	18072711
28014201	Kabi Help advance plus	H095SE	18073111
28014301	Kabi Help advance plus	H106SF	18083113
28014301	Kabi Help advance plus	H106SF	18090414
28014401	Kabi Help advance plus	H089SG	18071711
28014401	Kabi Help advance plus	H106SG	18082811
28010241	Kabi Help duo	I092RR	19070211
28010351	Kabi Help duo	I092RP	19070211
28010351	Kabi Help duo	I152RP	19101811
28100651	Kabi Help duo	I117RL	19080211
28101331	Kabi Help duo	I117RN	19080211
28013021	Kabi Help uno	H023	18022711
28013021	Kabi Help uno	H095RB	18072711
28013021	Kabi Help uno	I164RB	19103113
28013051	Kabi Help uno	I164RC	19103113
28013201	Kabi Help uno	H023	18022711
28013201	Kabi Help uno	H083RE	18070611
28013201	Kabi Help uno	H125RE	18100511
28013301	Kabi Help uno	H023	18022711
28013301	Kabi Help uno	H125RF	18100511
151291	Nutri-bag eva	H052	18042411
151410	Nutri-bag eva	H042	18040411
151410	Nutri-bag eva	H092	18080711
151410	Nutri-bag eva	H092	18082212
151410	Nutri-bag eva	H116	18092111
151410	Nutri-bag eva	H121	18100211
151410	Nutri-bag eva	I141	19092411
151410	Nutri-bag eva	I141	19092613
151410	Nutri-bag eva	I167	19110811
151410	Nutri-bag eva	M004	21012114
151411	Nutri-bag eva	H001	18010911
151411	Nutri-bag eva	H052	18050411
151411	Nutri-bag eva	H080	18062911
151411	Nutri-bag eva	H121	18100211
151411	Nutri-bag eva	I110	19072311
151411	Nutri-bag eva	I144	19100111
151420	Nutri-bag eva	H092	18072411
151420	Nutri-bag eva	H121	18100211
151420	Nutri-bag eva	I006	19011511
151420	Nutri-bag eva	I050	19040911
151420	Nutri-bag eva	I141	19092613

REF.	NAME	LOT	STERILISATION BATCH
151420	Nutri-bag eva	I155	19101111
151420	Nutri-bag eva	I162	19102911
151420	Nutri-bag eva	L191	21010814
151421	Nutri-bag eva	H092	18072711
151421	Nutri-bag eva	H135	18102613
151421	Nutri-bag eva	I121	19080611
151421	Nutri-bag eva	I133	19091711
151422	Nutri-bag eva	H001	18010911
151422	Nutri-bag eva	H052	18042011
151422	Nutri-bag eva	H052	18042411
151422	Nutri-bag eva	H052	18050411
151422	Nutri-bag eva	H080	18062911
151422	Nutri-bag eva	H121	18100211
151422	Nutri-bag eva	I110	19072311
151422	Nutri-bag eva	I155	19101111
151422	Nutri-bag eva	I162	19102911
151422	Nutri-bag eva	I167	19110811
151423	Nutri-bag eva	H092	18072411
151423	Nutri-bag eva	H092	18072711
151423	Nutri-bag eva	H116	18092111
151423	Nutri-bag eva	I144	19100111
151423	Nutri-bag eva	I155	19101811
151423	Nutri-bag eva	I167	19110811
151423	Nutri-bag eva	I179	19112211
151423	Nutri-bag eva	M004	21012211
151427	Nutri-bag eva	H092	18072411
151440	Nutri-bag eva	H052	18050411
151440	Nutri-bag eva	I006	19011511
151440	Nutri-bag eva	I094	19070211
151440	Nutri-bag eva	I133	19091711
151440	Nutri-bag eva	I162	19102911
151440	Nutri-bag eva	L191	21010812
151440	Nutri-bag eva	L191	21010814
151440	Nutri-bag eva	M004	21012114
151440	Nutri-bag eva	M004	21012211
151446	Nutri-bag eva	H092	18072711
151446	Nutri-bag eva	H103	18080711
151446	Nutri-bag eva	H103	18082212
151446	Nutri-bag eva	I006	19011511
151446	Nutri-bag eva	I121	19080611
151446	Nutri-bag eva	I129	19090215
151447	Nutri-bag eva	H001	18010911
151447	Nutri-bag eva	H042	18040411
151447	Nutri-bag eva	H103	18082212
151447	Nutri-bag eva	H103	18082811
151447	Nutri-bag eva	I050	19040911
151447	Nutri-bag eva	I141	19092613
151447	Nutri-bag eva	I155	19101111

REF.	NAME	LOT	STERILISATION BATCH
151447	Nutri-bag eva	I162	19102911
151447	Nutri-bag eva	I173	19111416
151447	Nutri-bag eva	L144	20102311
151447	Nutri-bag eva	M004	21012114
151495	Nutri-bag eva	H052	18050411
151495	Nutri-bag eva	H103	18082212
151495	Nutri-bag eva	I006	19011511
151495	Nutri-bag eva	I129	19090215
151495	Nutri-bag eva	I155	19101111
151495	Nutri-bag eva	M004	21012114
151496	Nutri-bag eva	H092	18072011
151496	Nutri-bag eva	H092	18072411
151496	Nutri-bag eva	H121	18100511
151496	Nutri-bag eva	H135	18102613
151496	Nutri-bag eva	I006	19011811-1
151496	Nutri-bag eva	I133	19091711
151496	Nutri-bag eva	I141	19092411
151496	Nutri-bag eva	I155	19101811
151444	Nutri-bag multicapa	I094	19070211
151444	Nutri-bag multicapa	I162	19102911
151455	Nutri-bag multicapa	H103	18080711
151465	Nutri-bag multicapa	H103	18080711
151480	Nutri-bag multicapa	H001	18010911
151480	Nutri-bag multicapa	I110	19072311
151482	Nutri-bag multicapa	H001	18010911
151482	Nutri-bag multicapa	H042	18040411
151482	Nutri-bag multicapa	H052	18042011
151482	Nutri-bag multicapa	H103	18080711
151482	Nutri-bag multicapa	I167	19110811
151482	Nutri-bag multicapa	M004	21012114
151483	Nutri-bag multicapa	I133	19091711
151483	Nutri-bag multicapa	I162	19102911
151483	Nutri-bag multicapa	I162	19103113
151484	Nutri-bag multicapa	H001	18010911
151484	Nutri-bag multicapa	H042	18040411
151484	Nutri-bag multicapa	H052	18042011
151484	Nutri-bag multicapa	H052	18042411
151484	Nutri-bag multicapa	H103	18082212
151484	Nutri-bag multicapa	I133	19091711
151484	Nutri-bag multicapa	I155	19101811
151484	Nutri-bag multicapa	I167	19110811
151484	Nutri-bag multicapa	M004	21012114
151487	Nutri-bag multicapa	H001	18010911
151487	Nutri-bag multicapa	H052	18042411
151487	Nutri-bag multicapa	H121	18100211
151487	Nutri-bag multicapa	I173	19112211
151490	Nutri-bag multicapa	I094	19070211
151490	Nutri-bag multicapa	I144	19100111

REF.	NAME	LOT	STERILISATION BATCH
151490	Nutri-bag multicapa	I162	19102911
151490	Nutri-bag multicapa	M004	21012114
151491	Nutri-bag multicapa	I094	19070211
151502	Nutri-bag multicapa	H042	18040411
151502	Nutri-bag multicapa	I094	19070211
151502	Nutri-bag multicapa	I133	19091711

Enteral bags:

REF.	NAME	LOT	STERILISATION BATCH
6013G	Di Eto	H101	18073111
6013G	Di Eto	I138ZD	19100411
6020V	Di Eto	I171	19103113
151506	Nutri-bag enteral	H080	18062911
151507	Nutri-bag enteral	H103	18082212

Sets:

REF.	NAME	LOT	STERILISATION BATCH
151287	Connection set	I155	19101111
82M.L84	Connection set	I150	19103113
82M.NF84	Connection set	I171	19103113
82S.L31	Connection set	H078	18071711
82S.L31	Connection set	H097	18082212
82S.L31	Connection set	H118	18100911
82S.NF29	Connection set	I150	19103113
B103	Connection set	H120ZB	18100511
B103	Connection set	I170ZB	19103113
F.F.4202	Connection set	H060	18051811
F.F.4202	Connection set	I009	19011811-1
F.F4202	Connection set	I150	19101111
L.L701	Connection set	H060	18051811
L.L701	Connection set	I171	19103113
SPINOVER	Connection set	H005	18011611
SEP27	Extension set	H046	18042011
H9380003	Filling set	H028ZA	18022711
H9380003	Filling set	H047ZA	18041011
H9380003	Filling set	H047ZA	18041311
H9380003	Filling set	H057ZA	18050811
H9380003	Filling set	I070ZA	19052111
H9380003	Filling set	I172ZA	19111416
H9380003	Filling set	L149ZA	20101311
H9380003	Filling set	M006ZA	21012211
B150.4S	Preparation set	H046	18042011
82.0001F	Transfer set	I174	19111416
82.0001F	Transfer set	L198	21011211

## ANNEX 2 – REPLY FORM

Please read in conjunction with the FSN recall letter dated April 20, 2021. Please return the completed form by emailing it to info@diffuplast.it.

Company name:	
Address:	
Contact name:	
Email:	

- I acknowledge that I have received, read and understood the Field Safety Notice.
- I have checked our facility's stock and I would like to return the following items:

Code	Batch	Quantity

Signature and date: \_\_\_\_\_