HENRY SCHEIN®
Henry Schein, Inc. • 135 Duryea Road • Melville, NY 11747

Date: November 16th, 2021 Control Number: 5866

FIELD SAFETY CORRECTIVE ACTION (FINAL)

Dear Competent Authority,

Henry Schein was notified that some sterilization certificates complied by the OEM's sterilization service provider, Steril Milano, have a quality issue and the sterility was compromised. The non-compliant sterilization certificates impact Henry Schein's private label products, supplied by Private-Label manufacturing partner F.M S.p.A.. Henry Schein had initiated the following **immediate actions** on April 21st 2021, and triggered international recall of the impacted specific products lots (listed on **Page 3-4).**

We, hereby, confirm that November 15th 2021 is the closing date of Field Safety Corrective Actions carried out for Control #5866 in all affected markets. We confirm the withdrawal and recall of the impacted products from all affected markets. We confirm that all the impacted end customers and business partners of Henry Schein in ALL affected countries had been notified of this Recall (Control #5866) via initial Field Safety Notice (FSN) in April 2021. Follow-up FSN attempts had been sent to our impacted end customers and business partners. Henry Schein had received the first customer responses in the EU starting from April 28th 2021. Until the closing date of the Recall on November 15th 2021, more than 40 responses from impacted customers in the EU had been received.

To completely close the Control #5866, Henry Schein had initiated Field Safety Corrective Actions (FSCA) Final Report filing at the Competent Authorities in ALL countries in the European Union (EU) where the affected devices are on the market (listed on **Page 2).** Henry Schein filed the completed Final FSCA - "Report Form - Field Safety Corrective Action Medical Devices Vigilance System (MEDDEV 2.12/1 rev 7)" at Competent Authorities in ALL affected EU countries. Field Safety Notice (FSN, *HSI #Control 5866_EN.pdf*) and Final Field Safety Corrective Action (FSCA, *FSCA - HSI# Control 5866_Final.pdf*) of Control #5866 had been shared with Competent Authorities together with the "Report Form".

Immediate actions:

- With the awareness of the situation, further distribution of the affected products was immediately stopped.
- A "warehouse alert" was sent to our warehouses to immediately separate and quarantine any goods that may be in stock.
- The parent company and manufacturer Henry Schein Inc. immediately contacted the OEM contract manufacturer to request a risk analysis.
- As part of a risk analysis, a check was made to determine whether other OEM manufacturers are affected. Other than Deltamed Spa. no other OEM was identified.
- A review of the existing complaint data has revealed that no further incidents have been reported in connection with this matter.
- The sales units were immediately informed of the measures required to ensure that affected customers are informed. The customer letter attached to them was provided for this purpose.
- All affected products will initially be blocked locally and recalled accordingly.

Corrective actions performed as follows:

- Supplier qualification and monitoring has been optimized and a supplier auditor has been hired to monitor contract manufacturers
- A procedural instruction on "Conducting supplier audits and determining risk potential for private label manufacturers" has been implemented since April 20, 2021.
- On this basis, an audit program has been developed to review contract manufacturers and started in April 2021 and was rolled out to continue monitor the quality performance of Henry Schein's contract manufacturers.

Information on corrective measures to prevent recurrence of the product deficiency in the future;

According to CAPA Plan already mentioned, the main measures implemented are qualification and monitoring of suppliers based on a risk-based approach. The implementation of the above- mentioned procedural instructions serve to minimize the risk so that such an incident can be avoided, and an appropriate selection of contract manufacturers is ensured

Twenty-one (21) EU countries (including UK and EEA countries) had been impacted

1. Austria
2. Belgium
3. Cyprus
4. Czech Republic
5. Denmark
6. Finland
7. France
8. Germany
9. Greece
10. Hungary
11. Ireland
12. Italy
13. Luxembourg
14. Netherland
15. Poland
16. Romania
17. Slovenia
18. Spain
19. Sweden
20. Switzerland
21. United Kingdom

TABLE A – Affected Product		
HSI Product Code	**Product Description**	**Lot Number**
900-8450	Maxima Vented I.V. Infusion Set with injection bulb	16E158
		16H084
		16I091
		16J119
		16K077
		16L080
		17B175
		17H117
		18C070
		18D069
900-8451	Maxima Vented I.V. Infusion Set without injection bulb, Luer Lock	16H081
		16H093
		16J123
		16K101
		17H118
		18B040
		18C066
900-8452	Heidelberg extension line 75cm	16E155
		16J075
		16K102
		17H114
		17K019
		17L038
		18A057
		18D072
900-8453	Withdrawal cannula, luer lock (Taky-Spike-Plus)	16J121
		16K078
		17B171
		17C073
		17D029
		17D119
		17E134
		17K017
		18C059
		18E019
		18L063
		18L082
		19C111
		19D109
		19F070

TABLE A – Affected Product		
HSI Product Code	**Product Description**	**Lot Number**

900-8454	3-way stop cock, red	16E154
		16J117
		17B172
		17K018
900-8455	Bottle transfer cannula	16E153
		16H086
		17B169
		17F058
		17G056
		17K039
		18A056
		18L062
		19E076
900-8456	Bottle transfer cannula	16F069
		16G136
		16I055
		17C114
900-8918	Heidelberg extension line 30cm	16E020
		16E151
		16K100
		17H116
		17K021
		17L039
		18B039
		18C072
900-8919	Heidelberg extension line 100cm	17H113
		18B038
		18C071
		18D071
900-8920	Heidelberg extension line 140cm	16E156
		16E157
		16F067
		16F068
		16G133
		16J074
		16J102
		17D147
		17H115
		17K020