FIELD SAFETY CORRECTIVE ACTION

Number:	**5690**	Action:	**Removal**	Unit Name:	**Molecular**
Product Name:	NUCLISENS® Magnetic Silica				
Issue Date:	**01-JUL-2022**	Manufacturing Site:	**Grenoble**	Required Actions	

Section A: Details

Affected Product

- **System:** N/A
- **REF:** 280133
- **Lot/Serial:** See Table 1 and Table 2
- **Expiry:** See Table 1 and Table 2
- **Product:** NUCLISENS® Magnetic Silica
- **GMDN Code:** 52521
- **Unique Device Identifier:** 03573026139339

Manufacturing Beginning & End Date: See Table 1 and Table 2

Distribution Beginning & End Dates: N/A

Quantity on hand: See Table 1 and Table 2

Date of Decision to take Action in the Field: 27-JUN-2022

Table 1: List of lots impacted by the issue and distributed

REF #	Product name	Lot Number	Manufacturing date	Expiry date	Total number of devices manufactured	Quantity on hand	PSS number
280133	NUCLISENS® Magnetic Silica	Z012ME1MS	13-JAN-2022	28-DEC-2022	362	0	5683
280133	NUCLISENS® Magnetic Silica	Z012MF1MS	13-JAN-2022	28-DEC-2022	356	0	5683
280133	NUCLISENS® Magnetic Silica	Z012MH1MS	13-JAN-2022	28-DEC-2022	360	0	5683
280133	NUCLISENS® Magnetic Silica	Z012MK1MS	05-JAN-2022	28-DEC-2022	273	0	5683
280133	NUCLISENS® Magnetic Silica	Z012ML1MS	08-DEC-2021	28-NOV-2022	361	0	5683
280133	NUCLISENS® Magnetic Silica	Z012NE1MS	06-DEC-2021	28-NOV-2022	311	0	5683
280133	NUCLISENS® Magnetic Silica	Z012ND1MS	08-DEC-2021	28-NOV-2022	362	0	5683
280133	NUCLISENS® Magnetic Silica	Z012NC1MS	06-DEC-2021	28-NOV-2022	358	0	5683

280133	NUCLISENS® Magnetic Silica	Z012NB1MS	06-DEC-2021	28-NOV-2022	357	1	5683
280133	NUCLISENS® Magnetic Silica	Z013AK1MS	25-FEB-2022	28-JAN-2023	355	221	5687
280133	NUCLISENS® Magnetic Silica	Z013AL1MS	01-MAR-2022	28-JAN-2023	310	0	5687

Table 2: List of lots impacted and not yet distributed

REF #	Product name	Lot Number	Manufacturing date	Expiry date	Total number of devices manufactured	Quantity on hand	PSS number
280133	NUCLISENS® Magnetic Silica	Z012MG1MS	15-DEC-2021	28-NOV-2022	360	360	5683
280133	NUCLISENS® Magnetic Silica	Z013AG1MS	25-FEB-2022	28-JAN-2023	360	357	5687
280133	NUCLISENS® Magnetic Silica	Z013AF1MS	25-FEB-2022	28-JAN-2023	358	358	5687
280133	NUCLISENS® Magnetic Silica	Z013AH1MS	25-FEB-2022	28-JAN-2023	359	359	5687

Name and Address of Legal Manufacturer

Name & Address of Recalling Firm: bioMérieux SA
F-69280 Marcy l'Etoile, France

Name & Address of Manufacturing Site: bioMérieux SA
5 rue des berges
38024 GRENOBLE

Product Intended Use

IFU 043969 – 04:
The NUCLISENS® easyMAG® accessory products are reagents and disposables to be used with the BIOMÉRIEUX instruments which mention these products in their User Manuals. They enable the automated extraction (purification and concentration) of total nucleic acids (RNA/DNA) from homogeneous human biological fluid samples. These products are intended for in vitro diagnostic use by healthcare professionals.

Description of the Issue

Is there a PSS associated with this FSCA? YES ■ NO ☐ PSS Number: 5683 and 5687_____
Is this FSCA associated with a customer complaint? YES ■ NO ☐
Customer Complaint Number(s): CN-353615, CN-353613, CN-350316, CN-353340, CN-353916, CN-353914, CN-353919, CN-350300, CN-351593, CN-357232, CN-357222, CN-359782, CN-362856,CN-366094
Investigation Reference Number: **INV-12468**

Since May 2022, bioMérieux received customer's complaints for contamination of extraction reagents with Legionella spp nucleic acids using easyMAG® and EMAG® extraction systems.

bioMérieux initiated an investigation to assess product issue and identify the root-cause, while the investigation is still ongoing the following were identified:

- After testing of all individual extraction reagents on a NESTED PCR for Legionella spp and for bacterial DNA detection (16S rDNA PCR), the investigation confirmed the presence of nucleic acid contamination of silica raw material 4.33 and 4.34, but also reveal the presence at a very low level of bacterial DNA for silica raw material 4.32. The three contaminated raw material lots were possibly used to manufacture fifteen (15) lots of NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 and Table 2.

The other NUCLISENS® reagents references and the MES buffer used to dilute the silica raw material are not contaminated.

- The silica were streaked on culture media (Tryptone Soya Broth (TSB) and Columbia Blood Agar (COS) medium) in order to identify if the contamination was only coming from nucleic acid and/or "alive" bacteria. The TSB and COS culture media did not allow the growth of bacteria. Buffered charcoal yeast extract (BCYE) dedicated for legionella, allowed the growth after 5 days of few colonies on 4.33 and 4.34 raw material only). After identification, the bacteria were mainly from the family of Bacillus (environmental bacteria), no legionella spp bacteria was detected. Thus, the silica lots are mainly contaminated by nucleic acid from bacteria and in particular from legionella spp and alive bacteria from Bacillus family but at a very low level (so not considered as a contamination as our products are not claimed DNA free)

- The Product Instructions for Use of extraction reagents request to the customers to always perform a negative extraction controls in each extraction run:
IFU 043969 – 04: "To ensure the proper proceedings of the extraction, always use the appropriate controls to control the extraction procedure:
    - A positive extraction control (sample/material positive to the target).
    - A negative extraction control (sample/material negative to the target).

An Internal Control (IC): obtained by transferring a fixed quantity of target control in each sample to extract. The Internal Control must be added before the isolation steps to be purified along with the target, and then be amplified and/or detected. An Internal Control is necessary for any application that can lead to false negative results."
•Therefore, with the use of extraction negative control, the run should be invalid in case of a positive result on a negative control and no result can be obtained.

- For customer who does bacterial research detection like Legionella spp, 16S rDNA, 23S RNA or others bacterial applications, the contamination will be detected with the negative extraction control (negative extraction control will be positive) as required in the Product Instruction for Use.

- The investigation confirmed that the use of contaminated silica does not have any impact on others applications. Key representative tests on PCR/RT PCR / NASBA applications (DNA/RNA virus & bacteria and various specimen type and extraction protocols) have been tested for clinical and Industry diagnostic. No impact has been observed on the sensitivity/specificity and quantification of all the parameter tested.

In conclusion,
- The root cause of the referenced issue is linked to raw material silica coming from a Supplier, and has to be determined at supplier level.
- The issue impacts only applications for bacterial nucleic acids detection, especially Legionella spp, and other applications like 16S rDNA, 23S rDNA. All applications for which the extraction negative controls are valid (negative status) are not impacted by the issue.
- The only hazard associated to the referenced issue is a no result leading to delayed result. There is no risk of false result caused by the issue as a negative extraction control has to be run to assess the level of contamination. Therefore, the issue should always be detected by the customer.
- Few cultivable/growing bacteria, mainly from the family of Bacillus (environmental bacteria), were detected in contaminated silica raw material, no cultivable/growing Legionella spp bacteria was detected. In conclusion, the silica lots are mainly contaminated by nucleic acid from bacteria and in particular from Legionella spp. The investigation confirmed that there is no safety risk for users.

Root cause: The root cause has not yet been identified

CAPA Determination: A CAPA PR#1780723 has been initiated to identify the root-cause and prevent the issue to recur

Field Action Decision:
The impacted products listed in Table 1 and Table 2 are used in clinical, Industry and veterinary backgrounds.
Considering the overall risk that is moderate, the FA Board determined that a Field Safety Corrective Action (FSCA#5690) would be appropriate to inform customer having received or who will receive lots of NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 and Table 2 about the issue (no result leading to possible delayed results), inform them that they can continue the use of the impacted lots of the NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 and Table 2 except for bacterial nucleic acid detection applications especially Legionella spp, and other applications such as 16S rDNA, 23S rDNA. Also confirm them, that all applications for which the negative controls is valid, can be safety performed.

The same actions will be implemented whatever the type of use (clinical/veterinary/industrial). All impacted customers will receive the same Urgent Field safety Notice.

Short-term Actions:

- **Actions required at subs/distributors levels:**

- Translate and Send the Urgent field Safety Notice associated to FSCA#5690 to all customers having received and **who will receive** impacted lots from NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 and Table 2

- Discard all lots listed in Table 1 under PSS 5683 and PSS 5687 which are remaining in their inventory.

- Inform them that they may receive for a short period of time lots listed in Table 1 and Table 2, including an insert that could be released on the market

- Inform them that conforming lots are also and readily available.

- Inform them that a credit note will be accepted for customers that cannot use the impacted lots on their bacterial applications

- **Actions required at customer level:**

- bioMérieux will inform customers having received and who will receive impacted lots of NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 and Table 2 about the issue

- Inform them that they can continue the use of the impacted lots of the NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 except for bacterial nucleic acid detection applications especially Legionella spp, and other applications such as 16S rDNA, 23S rDNA.
Also confirm them, that all applications for which the negative controls is valid, can be safety performed.

- Ask them that in case of encountering invalid negative control, to stop using and discard the impacted lot, and to contact their local bioMérieux representative to order conforming lots.

- Inform them that they may receive for a short period of time lots listed in Table 1 and Table 2 with an insert. This insert will contain the same information as described just above.

- Ask them to discuss any concerns they may have regarding previously reported patients' results obtained with any of the lots listed in Table 1 (in case of negative control not performed as required per product Instructions for Use) with their Laboratory Medical Director to determine the appropriate course of action

Long-term Actions:
Finalize CAPA PR#1780723

Risk Assessment / Health Hazard Assessment

The risk for customer patient is no results potentially leading to delayed results. There is no risk of false results.

- According to BMX.1.018440 - Product Risk Analysis Extraction Reagents - Rev 5 the potential hazard identified for patient is No results according the fact that customer has to run appropriated controls during extraction run, such as negative control. If a negative control is positive, then the run is not valid, and results cannot be used and trust. The risk is then no results or delayed results. IFU version 043969-04 mentions to:
"QUALITY CONTROL
To ensure the proper proceedings of the extraction, always use the appropriate controls to control the extraction procedure:
- A positive extraction control (sample/material positive to the target).
- A negative extraction control (sample/material negative to the target).

- An Internal Control (IC): obtained by transferring a fixed quantity of target control in each sample to extract. The Internal Control must be added before the isolation steps to be purified along with the target, and then be amplified and/or detected.

• Define the occurrence of the issue following the conclusion of investigation results
P1 calculation (Probability of hazardous situation occurring): we consider the number of released lots produced with the impacted raw material, 100% are contaminated. 40 lots are available, so the probability is 15/40 = 0.375 so the P1 is assessed as **FREQUENT** (highest level).

o Immediate and Long Range Health Consequences:
The applications used downstream of NUCLISENS® easyMAG® or EMAG® systems can be very diverse. According to the complaints and the investigations described in section 2, the defect will only impact the following downstream applications: 16S rDNA PCR and legionella spp or other applications allowing detection of bacterial nucleic acid like 23S RNA.
Some downstream applications of Broad-range 16S or 23S rDNA PCR are done for research purposes and will not have patients and/or users impact. Broad-range 16S rDNA PCR can be used as an adjunct to microbiological diagnostics as a second line when infection of a sterile site is highly suspected, but culture and qPCR for the most likely pathogens have been proven negative. It can be clinically useful when other techniques give negative results, for example, in culture-negative endocarditis, septic arthritis, meningitis or long-line infections.

In addition to 16S rDNA, the gene coding for the large subunit ribosomal RNA (23S rDNA) has also been targeted for the development of PCR methods for bacterial detection. It can be targeted as a real-time pan-bacterial PCR method in blood. Quantification of total bacterial DNA in the bloodstream could be performed with 23S rDNA PCR.

However, the breadth of broad-range 16S or 23S rDNA PCR renders it vulnerable to contamination. All bacterial DNA present in a sample is amplified, including that which is unavoidably present in reagents, meaning low-level environmental contamination is impossible to eliminate entirely. The laboratories will therefore always run a negative control to assess the level of contamination. The defect should therefore always be detected and no “false positive results” should be caused by the defect.

The only remaining risk is therefore due to “delayed result” (due to the fact that the extraction would have to be performed again) or “no results” (due to the fact that there is not enough primary sample to perform the extraction again).

Legionella spp. are a common cause of community-acquired respiratory tract infections and an occasional cause of nosocomial pneumonia. An estimated 3 to 8% of all community-acquired pneumonias are caused by Legionella spp. The case-fatality rate for patients with legionellosis is 5 to 30%, with the elderly and immunocompromised patients at greater risk of death. It is not possible to clinically distinguish patients with Legionnaires' disease from patients with other types of pneumonia. The key to diagnosis is performing appropriate microbiologic testing when a patient is in a high-risk category. Legionnaires' disease is reportable is several countries including France. Legionella spp. can also cause Pontiac fever, It is a self-limited illness that does not benefit from antibiotic treatment. Patients usually recover within 1 week.
The most commonly used laboratory test for diagnosis of Legionnaires’ disease is the urinary antigen test (UAT). The UAT detects the most common cause of Legionnaires’ disease, L. pneumophila serogroup 1. However, all species and serogroups of Legionella are potentially pathogenic, so a patient with a negative urinary antigen result could have Legionnaires’ disease caused by other Legionella species or serogroups, which is why using culture, PCR and UAT in combination is recommended. Legionella detection by PCR provides a more rapid turnaround time and a higher sensitivity than culture. First line treatment does not always include Legionella-directed antibiotics (e.g., macrolides and respiratory fluoroquinolones) and this is why PCR is advantageous to have a quick turnaround time leading to earlier adequate therapy for the patient.
The laboratories are required to run a negative control to assess for contamination according to our IFU (User Manual - 161150-730 - D - fr - EMAG - Extraction Methods). The defect should therefore always be detected and no “false positive results” should be caused by the defect.

The risk determined for no result, related to delay (worst-case scenario) by the Product Risk Analysis Extraction Reagents rev4 is **SERIOUS**: negative impact on the diagnosis with no permanent deterioration on the patient or population state of health but requiring medical intervention to prevent permanent deterioration of the state of health
As legionnaire’s disease is a reportable disease, the defect could lead to an increase of reporting to competent authorities.
There could also be an impact by delaying the Legionella diagnosis caused by a water contamination and cause spreading of Legionella cases.

For other applications, this cannot be determined as there are many potential downstream applications for bacteria nucleic acid extraction, some of which could have Public Health implications.

There is no factor that mitigate the risk of no result for bacteria nucleic acids detection and specially Legionella spp, and other applications like 16S rDNA, 23S rDNA.

The control negative will be positive so the run will be invalid. It means that the extraction will need to be re-done either from the same patient' sample if the remaining volume is sufficient or from a newly collected sample.

The P2 (Probability of hazardous situation leading to harm) because of delayed result is therefore quoted as **PROBABLE**: Likely to occur multiple times (but not frequently) over the life of the product.

Table 3: Summary of the overall risk before implementing a Field Action:

P1 (Probability of hazardous situation occurring)	P2 (Probability of hazardous situation leading to harm)	P (Overall probability)	Severity	OVERALL RISK
FREQUENT	PROBABLE	PROBABLE	SERIOUS	**MODERATE**

Notification to the Regulatory Authority

Recipients of this notification must assess the product issue and any associated patient risk in accordance with local regulations to determine if it is reportable to their local regulatory authority. Notification to your regulatory authority must include device classification when required.

Product Distribution

Impacted countries regarding 5683 PSS are as below:

280133 - Z012ME1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AT01	BIOMERIEUX AUSTRIA GMBH	Austria	AT
	AU01	Biomerieux Australia Pty Ltd	Australia	AU/NZ
	BE01	bioMerieux Benelux SA/NV	Belgium	BE/LU
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	CZ01	BIOMERIEUX CZ S.R.O.	Czech Republic	CZ
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES/IC
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB/IE
	GR01	BIOMERIEUX HELLAS S.A.	Greece	GR
	HK01	BIOMERIEUX CHINA LIMITED	Hong Kong	HK
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	KR01	BIOMERIEUX KOREA CO., LTD	South Korea	KR
	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	RU02	BIOMERIEUX RUSS LLC,	Russian Fed.	RU
	TH01	BIOMERIEUX THAILAND LTD	Thailand	TH
Distributors	1039487	ISED N.V.	Dutch Antilles	AN
	1038017	ILEX MEDICAL LTD	Israel	IL

280133 - Z012MG1MS

No shipment

280133 - Z012MF1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	CA01	BIOMERIEUX CANADA INC	Canada	CA
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES/IC
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB
	GR01	BIOMERIEUX HELLAS S.A.	Greece	GR
	HK01	BIOMERIEUX CHINA LIMITED	Hong Kong	HK/MO
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	KR01	BIOMERIEUX KOREA CO., LTD	South Korea	KR
	RU02	BIOMERIEUX RUSS LLC,	Russian Fed.	RU
	SE01	BIOMERIEUX SWEDEN AB	Sweden	SE/NO
Distributor	1038017	ILEX MEDICAL LTD	Israel	IL

280133 - Z012MH1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AT01	BIOMERIEUX AUSTRIA GMBH	Austria	AT
	AU01	Biomerieux Australia Pty Ltd	Australia	AU/NZ
	BE01	bioMerieux Benelux SA/NV	Belgium	BE
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	CL01	BIOMERIEUX CHILE SpA	Chile	CL
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES/IC
	FR01	BIOMERIEUX S.A	France	FR
	HK01	BIOMERIEUX CHINA LIMITED	Hong Kong	HK
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	PL01	bioMerieux Polska Sp. z o.o.	Poland	PL
	SE01	BIOMERIEUX SWEDEN AB	Sweden	SE/DK
	SG01	BIOMERIEUX SINGAPORE Pte LTD	Singapore	SG
	TH01	BIOMERIEUX THAILAND LTD	Thailand	TH
Distributors	1036446	DIAMEDICA OÜ	Estonia	EE
	1038017	ILEX MEDICAL LTD	Israel	IL
	1100291	SIMED PERU S.A.C.	Peru	PE

280133 - Z012MK1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	BE01	bioMerieux Benelux SA/NV	Belgium	BE/LU
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES/IC
	FR01	BIOMERIEUX S.A	France	FR
	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	PT01	BIOMERIEUX PORTUGAL, LDA	Portugal	PT
	US01	BIOMERIEUX US	United States	US

280133 - Z012ML1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AU01	Biomerieux Australia Pty Ltd	Australia	AU
	BE01	bioMerieux Benelux SA/NV	Belgium	BE/LU
	CA01	BIOMERIEUX CANADA INC	Canada	CA
	CL01	BIOMERIEUX CHILE SpA	Chile	CL
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB
	HK01	BIOMERIEUX CHINA LIMITED	Hong Kong	HK
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	US01	BIOMERIEUX US	United States	US

280133 - Z012NB1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AU01	Biomerieux Australia Pty Ltd	Australia	AU
	BE01	bioMerieux Benelux SA/NV	Belgium	BE/LU
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB/IE
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	JP01	bioMerieux Japan LTD	Japan	JP
	KR01	BIOMERIEUX KOREA CO., LTD	South Korea	KR
	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	SE01	BIOMERIEUX SWEDEN AB	Sweden	SE/FI/NO
	US01	BIOMERIEUX US	United States	US
	ZA01	BIOMERIEUX SOUTH AFRICA PTY	South Africa	ZA
Distributors	1036446	DIAMEDICA OÜ	Estonia	EE
	1038017	ILEX MEDICAL LTD	Israel	IL
	1030995	YUNYCOM DOO	Serbia	RS
Direct Customer	1123993	I - TECH MALAWI	Malawi	MW

280133 - Z012NC1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AU01	Biomerieux Australia Pty Ltd	Australia	AU
	CA01	BIOMERIEUX CANADA INC	Canada	CA
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	CL01	BIOMERIEUX CHILE SpA	Chile	CL
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES/IC
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB/IE
	HK01	BIOMERIEUX CHINA LIMITED	Hong Kong	HK
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT

	SE01	BIOMERIEUX SWEDEN AB	Sweden	SE/NO
	SG01	BIOMERIEUX SINGAPORE Pte LTD	Singapore	SG
	ZA01	BIOMERIEUX SOUTH AFRICA PTY	South Africa	ZA/BW
Distributor	1030694	OKKAR THIRI COMPANY LIMITED	Myanmar	MM
Global Export	1091791	BOSTON UNIVERSITY	Zambia	ZM

280133 - Z012ND1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	BE01	bioMerieux Benelux SA/NV	Belgium	BE/LU
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB/IE
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	JP01	bioMerieux Japan LTD	Japan	JP
	KR01	BIOMERIEUX KOREA CO., LTD	South Korea	KR
	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	RU02	BIOMERIEUX RUSS LLC,	Russian Fed.	RU
	SE01	BIOMERIEUX SWEDEN AB	Sweden	SE/NO
	TH01	BIOMERIEUX THAILAND LTD	Thailand	TH
	ZA01	BIOMERIEUX SOUTH AFRICA PTY	South Africa	ZA
Distributors	1038017	ILEX MEDICAL LTD	Israel	IL
	1030995	YUNYCOM DOO	Serbia	RS

280133 - Z012NE1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AU01	Biomerieux Australia Pty Ltd	Australia	AU
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES/IC
	FR01	BIOMERIEUX S.A	France	FR
	GB01	BIOMERIEUX UK LTD	United Kingdom	GB/IE
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	KR01	BIOMERIEUX KOREA CO., LTD	South Korea	KR
	RU02	BIOMERIEUX RUSS LLC,	Russian Fed.	RU
	SE01	BIOMERIEUX SWEDEN AB	Sweden	SE/DK/NO
Distributors	1038017	ILEX MEDICAL LTD	Israel	IL
	1054476	MEDIGENE SDN BHD	Malaysia	MY
Global Health	1098054	UNDP Office in Zimbabwe	Zimbabwe	ZW

Impacted countries regarding 5687 PSS are as below:

280133 - Z013AF1MS

No Shipment

280133 - Z013AG1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiary	FR01	BIOMERIEUX S.A	France	FR

280133 - Z013AH1MS

No Shipment

280133 - Z013AK1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AU01	Biomerieux Australia Pty Ltd	Australia	AU
	CA01	BIOMERIEUX CANADA INC	Canada	CA
	FR01	BIOMERIEUX S.A	France	FR
	GR01	BIOMERIEUX HELLAS S.A.	Greece	GR
	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	ZA01	BIOMERIEUX SOUTH AFRICA PTY	South Africa	ZA
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	ES
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
Distributor	1100291	SIMED PERU S.A.C.	Peru	PE

280133 - Z013AL1MS

Type	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	NL01	BIOMERIEUX BENELUX BV	Netherlands	NL
	US01	BIOMERIEUX US	United States	US