IMMEDIATE MESSAGE TO:

1. **Directors of Pharmacy**
2. **Medical Directors NHS Boards**

14 September 2016

Dear Healthcare Professional

DRUG ALERT CLASS 4 No 13 2016: CAUTION IN USE: ECOLAB – KLERPACK BD SYRINGE MULTI-PACK

Please see the attached drug alert and field safety notice for onward transmission as below.

Can Directors of Pharmacy please forward this alert to:

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Can Medical Directors please forward this alert to:

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant clinics
- Chief Executives of NHS Boards

Thank you for your help.

Yours sincerely

GORDON CLARK
Pharmacy and Medicines Division

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

D R U G A L E R T

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 14th September 2016 EL (16)A/13 Our Ref: MDR 037-09/16

Dear Healthcare Professional,

EcoLab

Klerpack BD Syringe Multi-Pack

Ecolab are recalling batches of Klerpack BD Syringe Multi-Pack as the sterile packaging may contain small holes in the film of the pouch. If holes are present, the package integrity is compromised and there is a risk that the syringe may no longer be sterile. The affected syringe products and batches are listed in Appendix 1 (Ecolab Field Safety notice).

The objective of this Drug Alert is to make users of the syringes aware of the Field Safety Notice in order to:

- Quarantine affected stock of the syringes
- Perform a local risk assessment for unexpired medicinal products produced using the affected batches of syringes

The local risk assessment should take into account the following factors:

- Specific use of the syringe (such as use during the manufacturing/compounding process and/or the final closed container system)
- Nature of the medicinal product (such as expiry period; susceptibility to microbiological proliferation, or any inhibitory effect)
- Route of administration and patient population
- Likelihood of medicinal product shortage (is replacement stock or an alternative product available?); impact of shortage on patients
- Ecolab data indicates a high likelihood of syringe packaging being compromised. The holes cannot be detected visually.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully
Sandra Bax
Defective Medicines Report Centre
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London, SW1W 9SZ
Telephone +44 (0)20 3080 6574

LIFE SCIENCES

ECOLAB

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URGENT FIELD SAFETY NOTICE

According to MEDDEV 2.12/1 rev. 8 ANNEX 5

Commercial name of product:	**Klerpack BD Syringe Multi-Pack**
Product Code:	**See product listed in this letter**
Lot:	**See product listed in this letter**
Type of action:	**Field Safety Corrective Action**
Attention:	**Hospitals - Pharmacy, Nuclear Medicine/Radiopharmacy, Purchasing and Quality Departments** **Industry - Purchasing, Quality and Production Departments**

Date: 2nd September 2016

Dear Customer,

This field safety notice is to inform you of a Field Safety Corrective Action involving certain models of Ecolab Ltd Klerpack BD Syringe Multi Packs.

Details of affected devices:
Klerpack BD Syringe Multi Packs, affected product SKUs and lot numbers are listed in this letter.

Description of the problem:
Routine internal testing has identified that the sterile packaging may contain small holes in the film of the pouch. If holes are present, the package integrity is compromised and there is a risk that the syringe may no longer be sterile.

Actions to be taken by the user:
Please immediately examine your stock, check the stock against the stock numbers provided in this notice and promptly quarantine the affected products and product lots. If you have further distributed the affected product, please identify your customers and notify them at once of this Field Safety Corrective Action. We recommend that you include this Field Safety Notice with the notification to your customers. This Field Safety Corrective Action should be carried out at the user level. Please monitor and provide feedback on the actions taken by customers.

Please complete and return the enclosed response form by either fax or email as soon as possible, but **no later than 30th September 2016.**

Upon receipt of the completed response forms, we will issue a return material authorization (RMA) and ask that you return any unused product from the affected batch to Ecolab Ltd at the address listed on the attached form. We will issue a credit for the unused product upon receipt.

Transmission of this Field Safety Notice:

This notice has been provided to:

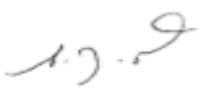
Local Competent Authorities

Intertek
Davy Avenue
Knowlhill, Milton Keynes
MK5 8NL, United Kingdom

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the Field Safety Corrective Action.

Please contact your local Customer Service or Sales Representative if you have any questions or concerns regarding this notification.

Yours faithfully



Andy Newsome
Vice President & General Manager EU, AP & MEA
Life Science

Phil Addison
Global Quality Director Life Science
Life Science

Products Affected by the Field Safety Notice

Product SKU	Product Name	Lot Numbers
3038080	Klerpack BD 1ml Syringes - EU/US Specification 10 packs x 5 pcs	4483SW4D, 3064SW3D, 3104SW1D 3236SW3D, 4246SW5D
3038090	Klerpack BD 10ml Syringes – EU/US Specification 10 packs x 5 pcs	2313SW3D, 1363SW5D, 2393SW3D 2433SW3D, 1483SW4D, 4503SW4D 5124SW1D, 4124SW4D, 5144SW2D 5144SW5D, 2274SW1D, 4354SW5D 2384SW1D, 5434SW2D, 2514SW2D 3045SW3D, 3075SW1D, 4125SW2D 5245SW4D, 1285SW2D, 5305SW3D 2435SW2D, 2435SW5D, 1485SW1D 2026SW3D, 2046SW2D, 4076SW1D 3086SW2D, 4086SW3D, 4126SW3D 3286SW1D
3038100	Klerpack BD 60ml Syringes – US Specification 10 packs x 5 pcs	3353SW1D, 3353SW2D, 1413SW4D 3433SW1D, 2473SW4D, 5493SW5D 2523SW2D, 2064SW3D, 5104SW2D 4104SW4D, 4164SW3D, 4164SW4D 5244SW2D, 1294SW2D, 1294SW3D 2304SW2D, 4374SW1D, 3374SW6D 1414SW3D, 1414SW1D, 4424SW1D 1464SW2D, 3494SW1D, 3494SW3D 4514SW3D, 4055SW1D, 3065SW3D 2095SW7D, 4125SW3D, 3165SW4D 4215SW3D, 4255SW2D, 4405SW4D 4465SW4D, 3515SW3D, 3016SW1D 2016SW5D, 1026SW4D, 1026SW1D 1216SW3D, 6216SW2D, 2286SW3D
3038110	Klerpack BD 1ml Syringes – EU/US Specification 10 packs x 10 pcs	5313SW3D, 3373SW3D, 2413SW2D 3433SW6D, 4453SW1D, 4513SW2D 2074SW5D, 4114SW4D, 4134SW3D 4194SW1D, 4254SW2D, 4264SW4D 4314SW3D, 4314SW1D, 1474SW2D 4484SW2D, 4045SW5D, 5065SW6D 4105SW4D, 3145SW4D, 6215SW3D 1255SW1D, 2285SW3D, 3305SW2D 1335SW2D, 4435SW2D, 1435SW1D 3505SW1D, 3036SW2D, 3046SW2D 1256SW2D, 2266SW2D
3038120	Klerpack BD 10ml Syringes - EU/US Specification 10 packs x 10 pcs	2343SW4D, 2343SW3D, 1343SW3D 1343SW1D, 1343SW2D, 3363SW3D 4393SW1D, 1453SW2D, 1473SW5D 6493SW4D, 5014SW1D, 4074SW1D 3074SW5D, 2114SW1D, 4144SW6D 3204SW3D, 5254SW2D, 4334SW2D 1394SW1D, 1394SW2D, 4434SW1D 5454SW1D, 4454SW4D, 2514SW1D 1514SW3D, 3045SW2D, 2065SW2D 2075SW2D, 3155SW6D, 1165SW2D 4225SW3D, 3225SW3D, 1285SW4D 4295SW5D, 3325SW2D, 2405SW5D 1425SW5D, 2455SW7D, 1465SW7D 2515SW3D, 3535SW3D, 2036SW4D 6106SW1D, 4256SW1D, 5266SW3D 3286SW4D, 1296SW1D
3039820	Klerpack BD 3ml Syringes - EU/US Specification 10 packs x 5 pcs	1463SW2D, 6493SW2D, 3044SW2D 5094SW2D, 2244SW5D, 5384SW1D 5045SW1D, 4145SW6D, 5245SW1D 5275SW2D, 1335SW1D, 2046SW4D 1076SW3D, 3286SW2D
3039830	Klerpack BD 5ml Syringes - EU/US Specification 10 packs x 5 pcs	4363SW1D, 6373SW3D, 5054SW1D 2144SW3D, 2234SW4D, 2244SW6D 1274SW1D, 5314SW5D, 1434SW1D 2474SW2D, 2065SW1D, 5265SW3D 2365SW1D, 3385SW1D, 4385SW1D 3415SW1D, 1076SW1D, 3236SW4D 4246SW6D, 3286SW3D

3039840	Klerpack BD 20ml Syringes - US Specification 10 packs x 5 pcs	4313SW2D, 1453SW5D, 6493SW5D 5034SW2D, 1064SW4D, 2064SW1D 1104SW2D, 3514SW3D, 4045SW2D 1145SW2D, 4255SW1D, 5275SW4D 5305SW2D, 4405SW1D, 2425SW2D 3495SW2D, 1046SW5D, 2076SW3D 3236SW2D, 4246SW4D
3039850	Klerpack BD 30ml Syringes - US Specification 10 packs x 5 pcs	5493SW4D, 5503SW2D, 1024SW3D 1054SW4D, 1184SW6D, 2184SW3D 5294SW2D, 5294SW1D, 2444SW1D 1494SW3D, 2055SW3D, 5085SW2D 3115SW2D, 4165SW1D, 5215SW3D 2245SW1D, 4295SW1D, 3295SW5D 4405SW2D, 2425SW3D, 2455SW6D 5495SW2D, 1236SW3D, 1276SW2D
3039870	Klerpack BD 3ml Syringes - EU/US Specification 10 packs x 10 pcs	1333SW1D, 5363SW1D, 3393SW3D 2443SW1D, 5463SW1D, 4513SW5D 3034SW5D, 3064SW5D, 3084SW5D 4084SW2D, 5134SW2D, 1144SW3D 4194SW1D, 4194SW5D, 2234SW2D 5264SW2D, 4294SW1D, 5314SW2D 3404SW1D, 5504SW1D, 3025SW1D 1045SW4D, 5045SW3D, 1075SW4D 5105SW2D, 5155SW3D, 2155SW3D 1225SW2D, 1235SW4D, 3245SW1D 4285SW3D, 4335SW1D, 4405SW3D 2425SW4D, 4445SW1D, 1525SW1D 4515SW5D, 3016SW2D, 2026SW1D 2046SW3D, 5096SW1D, 1126SW1D 1296SW2D
3039880	Klerpack BD 5ml Syringes - EU/US Specification 10 packs x 10 pcs	3333SW1D, 2363SW4D, 3393SW1D 5413SW1D, 4433SW2D, 1473SW1D 1473SW4D, 2513SW1D, 3024SW2D 4044SW1D, 5054SW3D, 4064SW3D 5114SW1D, 5114SW3D, 3144SW4D 5184SW4D, 2244SW7D, 3264SW2D 1274SW4D, 2474SW3D, 1514SW1D 4025SW3D, 2045SW4D, 2045SW3D 2075SW1D, 1115SW2D, 3155SW1D 2185SW5D, 2235SW1D, 3245SW2D 4285SW4D, 2335SW1D, 4385SW2D 1425SW6D, 1455SW4D, 3515SW1D 3026SW1D, 2026SW4D, 5056SW1D 2086SW1D, 1106SW1D, 4106SW3D 3196SW6D, 3236SW5D
3039890	Klerpack BD 20ml Syringes - US Specification 10 packs x 10 pcs	1313SW4D, 3413SW3D, 3453SW2D 1523SW1D, 2064SW2D, 2064SW6D 5074SW3D, 1094SW3D, 2104SW3D 2194SW4D, 2194SW6D, 2234SW6D 4274SW4D, 4274SW5D, 3324SW2D 4324SW2D, 1444SW1D, 3474SW4D 3474SW3D, 3474SW5D, 4514SW14 3035SW1D, 1065SW1D, 1085SW1D 3075SW3D, 2125SW1D, 2165SW1D 3225SW2D, 3235SW1D, 2295SW1D 3295SW1D, 3305SW3D, 2335SW2D 2515SW2D, 2535SW3D, 1016SW3D 2016SW2D, 5016SW4D, 2046SW1D 5046SW1D, 4066SW8D
3039900	Klerpack BD 30 ml Syringes - US Specification 10 packs x 10 pcs	4313SW3D, 2343SW6D, 3343SW1D 2363SW1D, 2403SW2D, 1423SW1D 3463SW2D, 2503SW2D, 1503SW2D 5024SW2D, 1074SW1D, 1104SW5D 2134SW3D, 3184SW3D, 3184SW5D 2234SW7D, 2264SW4D, 2264SW2D 1284SW2D, 1284SW3D, 1304SW1D 2444SW3D, 4474SW3D, 3514SW5D 3055SW2D, 2095SW3D, 2125SW3D 3165SW2D, 1225SW3D, 2245SW5D 5265SW5D, 4295SW2D, 4445SW3D 4435SW4D, 2485SW1D, 2036SW1D 1046SW2D, 2246SW2D

3039910	Klerpack BD 60ml Syringes - US Specification 10 packs x 10 pcs	3323SW3D, 1363SW1D, 2383SW3D 3403SW3D, 2433SW4D, 3463SW3D 2483SW3D, 2503SW3D, 2513SW2D 2024SW1D, 2044SW1D, 2064SW4D 3134SW6D, 2174SW2D, 4184SW1D 2234SW8D, 2294SW3D, 2294SW2D 2294SW1D, 2334SW1D, 2364SW2D 2364SW3D, 4374SW3D, 2464SW2D 4494SW2D, 4494SW3D, 3065SW5D 2105SW2D, 2135SW3D, 1175SW3D 3225SW1D, 2245SW4D, 1265SW1D 3365SW5D, 3365SW2D, 4425SW4D 2445SW1D, 1475SW2D, 5465SW2D 1505SW2D, 2505SW1D, 2505SW2D 2036SW6D, 4116SW2D
3039920	Klerpack BD 1ml Syringes - EU/US Specification 10 packs x 25 pcs	2333SW1D, 6343SW6D, 2353SW1D 1383SW3D, 3443SW4D, 3034SW2D 3054SW4D, 3084SW1D, 5174SW1D 4224SW2D, 4504SW1D, 2025SW3D 1075SW2D, 4105SW8D, 4145SW3D 6215SW1D, 2265SW1D, 5285SW2D 1435SW5D, 3036SW1D, 3056SW5D
3039940	Klerpack BD 3ml Syringes - EU/US Specification 10 packs x 25 pcs	4333SW5D, 1363SW3D, 3403SW1D 2403SW3D, 4443SW3D, 4014SW3D 4054SW4D, 3074SW3D, 3094SW3D 3304SWD2, 5504SW5D, 5045SW4D 6215SW2D, 3235SW3D, 3265SW2D 3335SW1D, 4375SW1D, 415SW4D 1146SW1D, 4146SW2D, 2166SW2D
3039960	Klerpack BD 5ml Syringes - EU/US Specification 10 packs x 25 pcs	1443SW6D, 2463SW2D, 5473SW3D 4503SW2D, 3503SW2D, 4503SW3D 5084SW2D
3039980	Klerpack BD 10ml Syringes - EU/US Specification 10 packs x 25 pcs	4333SWSD, 4373SW2D, 5503SW1D 4024SW2D, 4044SW5D, 5064SW3D 4204SW4D, 2224SW2D, 3274SW1D 1324SW4D, 5354SW2D, 3394SW2D 5434SW3D, 3464SW8D, 1494SW1D 3514SW1D, 4075SW4D, 4135SW5D 7175SW1D, 4205SW4D, 1255SW5D 4325SW1D, 5325SW2D, 2365SW6D 4365SW1D, 4385SW3D, 2445SW4D 1465SW1D, 1475SW4D, 4475SW3D 2475SW3D, 4525SW2D, 2535SW1D 4116SW1D, 2156SW4D, 2166SW1D 4176SW2D,
3040000	Klerpack BD 20ml Syringes - US Specification 10 packs x 25 pcs	4403SW4D, 5423SW1D, 3463SW1D 1503SW1D, 1044SW2D, 1044SW1D 5274SW2D, 5324SW1D, 4514SW2D 3035SW3D, 2085SW2D, 3115SW1D 4155SW5D, 1295SW3D, 2315SW1D 5355SW2D, 5375SW3D, 1445SW2D 1465SW5D, 2495SW4D, 1515SW3D 2535SW2D, 4535SW1D
3040020	Klerpack BD 30ml Syringes – US Specification 10 packs x 25 pcs	5323SW1D, 4413SW3D, 2443SW3D 1483SW6D, 3264SW1D, 1304SW2D 1334SW5D, 1464SW1D, 2494SW1D 3065SW2D, 2095SW6D, 2145SW1D 3165SW3D, 1185SW1D, 3205SW1D 4295SW3D, 4305SW1D, 4026SW3D 2056SW4D, 2066SW3D, 2076SW2D 1316SW3D

3040040	Klerpack BD 60mlSyringes - US Specification 10 packs x 25 pcs	3333SW3D, 2373SW2D, 7393SW1D 3413SW2D, 1433SW1D, 3453SW1D 2473SW1D, 4493SW1D, 1034SW1D 2054SW1D, 1084SW1D, 2094SW2D 2094SW1D, 3134SW3D, 3154SW2D 2154SW4D, 3154SW1D, 3174SW2D 2214SW2D, 4214SW1D, 3214SW4D 1254SW2D, 3264SW3D, 1284SW4D 2294SW4D, 2294SW5D, 2334SW2D 5374SW1D, 1384SW1D, 5424SW1D 3444SW1D, 3454SW1D, 5494SW3D 4055SW3D, 3095SW2D, 1105SW4D 1135SW1D, 2145SW3D, 2175SW3D 6175SW6D, 5175SW3D, 1245SW1D 2255SW2D, 4345SW2D, 5345SW4D 5345SW3D, 4365SW3D, 2375SW1D 1375SW3D, 2375SW2D, 3375SW6D 2405SW1D, 3395SW1D, 6395SW5D 2395SW1D, 2395SW2D, 2405SW2D 1425SW1D, 3435SW1D, 2485SW2D 4505SW1D, 3515SW2D, 3056SW1D 4066SW9D, 4306SW2D, 6336SW2D
3040060	Klerpack BD 1ml Syringes - EU/US Specification 10 packs x 50 pcs	3313SW2D, 5343SW2D, 7393SW4D 4423SW6D, 5443SW2D, 4473SW1D 4184SW5D, 5224SW4D, 3175SW1D 5185SW4D, 3265SW3D, 4275SW1D 3335SW2D, 1345SW1D, 3046SW1D 4066SW7D, 2076SW4D
3040070	Klerpack BD 3ml Syringes - EU/US Specification 10 packs x 50 pcs	6343SW2D, 4343SW1D, 4343SW3D 4393SW2D, 5393SW1D, 6493SW3D 1513SW4D, 5513SW1D, 4064SW1D 4104SW1D, 1184SW2D, 4244SW1D 4254SW5D, 4294SW3D, 4384SW1D 4424SW3D, 2474SW1D, 1055SW2D 5105SW4D, 4135SW3D, 2155SW5D 3435SW3D, 4455SW6D, 4515SW4D 2036SW5D, 4046SW3D
3040080	Klerpack BD 5ml Syringes - EU/US Specification 10 packs x 50 pcs	3343SW4D, 4423SW1D, 5483SW1D 4034SW2D, 1124SW3D, 4144SW2D 3204SW1D, 2224SW4D, 1274SW5D 1324SW2D, 3434SW1D, 5484SW2D 1514SW2D, 4115SW2D, 3155SW5D 2195SW1D, 3235SW5D, 4505SW4D 4535SW1D, 4046SW6D, 1096SW1D
3040100	Klerpack BD 10ml Syringes - EU/US Specification 10 packs x 50 pcs	2324SW1D, 1364SW2D, 1394SW4D 3474SW1D, 4045SW1D, 1125SW1D 4175SW1D, 4195SW1D, 4195SW2D 3255SW1D, 1295SW5D, 2305SW3D 4375SW4D, 3415SW3D, 2455SW2D 3495SW1D, 2036SW3D, 1086SW3D 3106SW2D, 5146SW1D, 4166SW3D
3040120	Klerpack BD 20ml Syringes - US Specification 10 packs x 50 pcs	2423SW3D, 2493SW2D, 5044SW2D 2104SW5D, 1214SW1D, 5284SW1D 1334SW2D, 3374SW2D, 4394SW1D 2434SW1D, 3464SW4D, 3464SW1D 3464SW2D, 3464SW3D, 1055SW5D 3085SW1D, 3125SW1D, 1145SW3D 2165SW2D, 3165SW1D, 4195SW3D 4195SW4D, 4235SW3D, 3255SW3D 3295SW3D, 5335SW1D, 2385SW5D 5475SW2D, 4505SW5D, 1016SW2D 5016SW3D, 4076SW2D, 1086SW1D
3040130	Klerpack BD 30ml Syringes - US Specification 10 packs x 50 pcs	1323SW4D, 2323SW3D, 2383SW3D 2423SW2D, 2473SW2D, 1054SW7D 2104SW4D, 3164SW3D, 3194SW1D 3194SW2D, 5284SW2D, 2304SW1D 5334SW2D, 2364SW1D, 4404SW1D 2494SW4D, 3065SW4D, 3125SW4D 4175SW2D, 5185SW2D, 3215SW2D 1056SW2D, 2066SW2D
3058710	Klerpacks BD 10ml Syringes – EU/US Specification / B Braun Blue Capped 10 packs x 50 pcs	2254SW2D, 2364SW4D
3058720	Klerpack BD 3ml Syringes – EU/US Specification / B Braun Blue Capped 10 packs x 50 pcs	3334SW1D

LIFE SCIENCES

Response Form - Klerpack BD Syringe Multi-Pack

Please fax or email this completed Response Form to:

TO:	Customer Service, Ecolab Ltd
FAX:	+44 (0) 2920 854 391
EMAIL:	infocc@ecolab.com
RE:	Field Safety Corrective Action – Klerpack BD Syringe Multi-Pack

CUSTOMER NAME:	
CONTACT PERSON:	
CONTACT PERSON PHONE:	

Please check ALL appropriate boxes

☐ I have read and understand the instructions provided in the Field Safety Notice dated 2nd September 2016.

☐ I have checked my stock and have returned inventory consisting of _____ cases.

Any adverse events associated with the affected product?: ☐ Yes ☐ No

If yes, please explain:

_____

Please check the appropriate box(es) to describe your business:

☐ wholesaler/distributor ☐ retailer

☐ re-packer ☐ manufacturer

☐ hospital/medical facility ☐ medical laboratory

Please confirm the quantity of recalled product remaining available for use at your facility:

Product SKU	Lot Number(s)	Quantity Originally Shipped to Customer	Quantity of Product Available for Return and Credit

PLEASE RESPOND BY 30TH SEPTEMBER 2016