Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System

(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? MHRA and those of the countries listed below	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 09/09/2020	
Reference number assigned by the manufacturer 2020-09-09/4480	
FSCA reference number assigned by NCA 2020/009/010/601/003	
Incidence reference number assigned by NCA N/A	
Name of the co-ordinating national competent authority (if applicable) N/A	
2. Information on submitter of the report	
Status of submitter ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Others (identify the role):	
3 Manufacturer information	
Name Welland Medical Ltd	
Contact name Arnya Traher	
Address Hydehurst Lane	
Postcode RH10 9AS	City Crawley
Phone +44 (0)1293 615455	Fax +44 (0) 1293 615411
E-mail arnyatraher@wellnadmedical.com	Country
4 Authorised representative information	

Name N/A no Authorised Rep currently in place	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5 National contact point information

National contact point name	
Name of the contact person	
Address	
Postal code	City
Phone	Fax
E-mail	Country

6 Medical device information

Class

- ☐ AIMD Active implants
- ☐ MDD Class III
- ☐ MDD Class IIb
- ☐ MDD Class IIa
- ☒ MDD Class I
- ☐ IVD Annex II List A
- ☐ IVD Annex II List B
- ☐ IVD Devices for self-testing
- ☐ IVD General

Nomenclature system (preferable GMDN) GMDN	Nomenclature code 46207
Nomenclature text Peristomal/periwound dressing	
Commercial name/brand name/make HydroFrame with Manuka Honey	
Model number (X)MHWAFH33	Catalogue number (X)MHWAFH33
Serial number(s) N/A	lot/batch number(s)

KL522	KM669
KL523	KM670
KL524	KM715
KL535	KN632
KL536	KN633
KL537	KN637
KL576	KN638
KL582	KN639
KM662	KN691
KM663	

Device Manufacturing date

Lot	Manufacture Date
KL522	Jun-20
KL523	May-20
KL524	Jun-20
KL535	Jun-20
KL536	Jun-20
KL537	Jun-20
KL576	May-20
KL582	Jun-20
KM662	Jun-20
KM663	Jun-20
KM669	Jul-20
KM670	Jul-20
KM715	Jul-20
KN632	Aug-20
KN633	Aug-20
KN637	Jul-20
KN638	Aug-20
KN639	Jul-20
KN691	Jul-20

Expiry date

Lot	Expiry Date
KL522	Jun-23
KL523	May-23
KL524	Jun-23
KL535	Jun-23
KL536	Jun-23
KL537	Jun-23
KL576	May-23
KL582	Jun-23
KM662	Jun-23
KM663	Jun-23
KM669	Jul-23
KM670	Jul-23
KM715	Jul-23
KN632	Aug-23
KN633	Aug-23
KN637	Jul-23
KN638	Aug-23
KN639	Jul-23
KN691	Jul-23

Software version number (if applicable)
N/A

Accessories/associated device (if applicable)
N/A

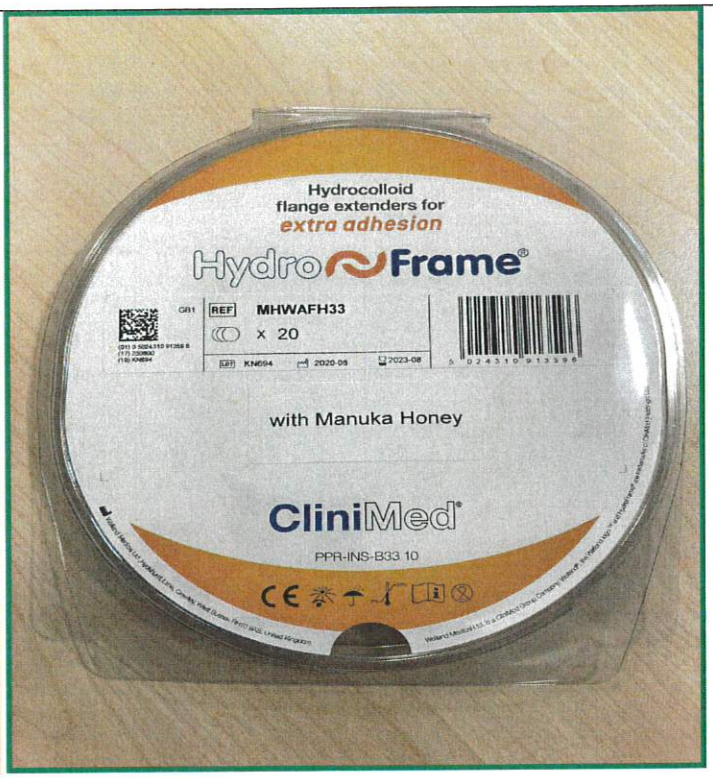
Notified body (NB) ID- number
N/A Class 1 Self-Certified

7 Description of FSCA

Background information and reason for the FSCA

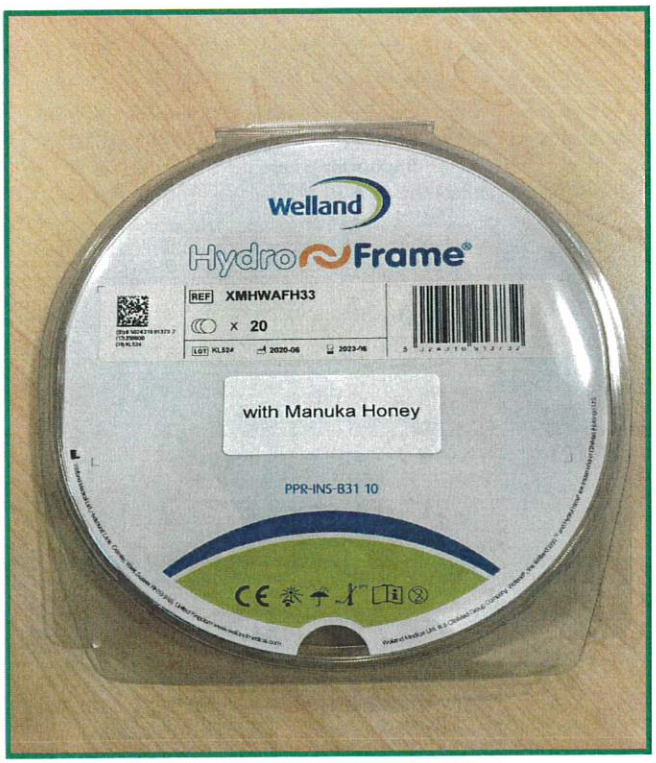
HydroFrame™ with Manuka Honey contains Manuka Honey and this is usually indicated on the insert. There is a slight possibility that users who are allergic to Manuka Honey may have a slight reaction to the product.

Description and justification of the action (corrective/preventive)
The product code is correctly pritned on the clam pack insert and Welland's Manuka Honey logo is correctly printed directly on the product. The IFU states to discontinue use if irritation occurs. End Users will be informed that the product contains Manuka Honey and Distributors will be asked to add additional label to indicate that Manuka Honey is present in the product.



X- Product Without Manuka Honey label

√- Product with Manuka Honey label



Welland

Advice on actions to be taken by the distributor and the user:

FSN ref 2020-09-09 to be issued advising distributers to make their cusotmers and users aware that the product contains Manuka Honey.
End Users will be informed that these batches contain Manuka Honey as do all batches of this code. Products held by distributers or in stock at other customers will have additional labels added either by Distributers themselves or by Welland Medical Ltd on return of products.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

N/A

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English ☐ FSN in national language ☐ Others (please specify):	☐ Draft ☐ Final

Time schedule for the implementation of the different actions:

Stock quarantined at distributers w/e 11/09/2020.

FSC to be issued to distributers w/e 11/09/2020.

Additional labels to be affixed to product at distributers or stock to be returned and relabelled starting w/e 11/09/2020

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

Within EEA, Switzerland and Turkey:

☐ AT	☐ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☐ DE	☒ DK	☐ EE	☐ ES
☒ FI	☐ FR	☒ GB	☐ GR	☐ HU	☐ IE	☐ IS	☐ IT	☐ LI	☐ LT
☐ LU	☐ LV	☐ MT	☒ NL	☒ NO	☒ PL	☐ PT	☒ RO	☐ SE	☐ SI
☐ SK	☐ TR								

Candidate Countries:
☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
Australia

8 Comments

This product and these batches are also sold in Italy, Spain, Germany and China but there is specific labelling for these countries that states the product contains Manuka Honey and therefore this FSCA is not applicable.

I affirm that the information given above is correct to the best of my knowledge.

Signature

Arnya Traher	Crawley, UK	09/09/2020
Name	City	Date