Precision b.v.

ID. 200-23-030-003 Rev. 20231114

Statement on shelf-life Comfort Marker 2.0 Safety Needle

Dear Sir, Madam,

The purpose of this letter is to inform you about the change in the shelf life of the Safety Needle.

It was discovered that Medical Precision did not complete the official route of submitting the change in shelf life of the Comfort Marker 2.0 Safety Needle, therefore 2 year shelf life needs to be changed to the 1 year shelf life, that was approved by our Notified Body.

Comfort Marker 2.0 Safety Needle, that is used together with device Comfort Marker 2.0 for placement of markings on human skin for radiotherapy treatments was CE certified by ECM for a shelf life of 1 year. All the tests, including real time aging that were performed to support 1 year shelf life initially claimed and were successful. Furthermore, same shelf-life confirmatory tests were also performed on a 2-year real-time aged Safety Needle with the goal to collect evidence for extension of the originally claimed shelf life of the Safety Needle to two years. All the performed tests were successfully passed by two year real aged samples. Consequently, it was deemed sufficient proof by the regulatory expert involved during that period with the Medical Precision B.V. to support the safe performance of the Safety Needle after increased storage time and extension of the shelf life of 2 years was implemented. However, Medical Precision did not officially submit this change to the overseeing Notified Body ECM for review and approval.

Medical Precision hereby states that there is no risk to the end users or patients in using Safety Needle with two year shelf life, since all the proof of it's safe performance after two years was collected and reviewed by the auditor. Nevertheless, as the prescribed change process was not followed, the extension of the shelf life was not accepted by the auditor and remediating actions to return the claimed for the Safety Needle to the approved by the ECM during CE certification one year was mandated.



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Batch number and expiry date of the Safety Needle can be identified on the label on the box that includes 25 Safety Needles or on the label on the packaging of each Safety Needle.

Batch number of the Safety Needle on the photos above is marked with green.

Shelf life of 2 years, that needs to be replaced by the expiry date stated in the table below can be identified is marked with the red box on the photos.

Effected batch numbers of the Safety Needle are stated in the table below, including a change in the expiry date to one year.

BATCH NUMBER OF THE SAFETY NEEDLE	DATE OF MANUFACTURING	EXPIRY DATE THAT SHOULD BE TAKEN INTO ACCOUNT	
20220525001	8-Jun-2022	31-May-203	
20220919001	9-Nov-2022	30-Sep-2023	
20221121001	28-Nov-2022	30-Nov-2023	
20230209001	16-Feb-2023	28-Feb-2024	
20230321001	5-Apr-2023	30-Mar-2024	

We invite you to take the following actions:

- Identify if any of the batches listed in the table are in stock
- Take into account the expiry date of one year, that is identified in the table per batch of Safety Needles

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- In case needles you have in stock are expired according to the new expiry date, please notify the manufacturer in order to arrange exchange of the Safety Needles

Please acknowledge receipt of this communication by returning the Annex I as soon as possible and no later than 30-Nov-2023.

We remain at your disposal for any questions or assistance.

Manufacturer contacts:

Medical Precision B.V.

Telfordstraat 9-30

8013RL Zwolle

The Netherlands

info@medicalprecision.nl

juha@medicalprecision.nl

Zwolle, 14-Nov-2023

Roland Kortenhorst, CEO

Signature:

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Annex I

FORM TO BE FILLED IN BY THE DISTRIBUTOR/ END USER

DISTRIBUTOR/END USER DETAILS	IN DI THE DISTRIBUTORY END USER
COMPANY NAME	
ADDRESS	
CONTACT NAME	
PHONE NUMBER	
EMAIL	
PLEASE IDENTIFY THE BATCH OF SAFETY N	EEDLE YOU HAVE IN STOCK AND THE QUANTITY
SAFETY NEDLE BATCH NUMBER	QUANTITY
20220525001	
20220919001	
20221121001	
20230209001	
20230321001	
INSTRUCTIONS FOR REPLACEMENT OPTION In case you decided the Safety Needles to saddress: Medical Precision B.V. Telfordstraat 9-30	N ship back to be replaced, please ship them to the following
8013RL Zwolle	
The Netherlands	
Name:	
Date:	
Place:	
Signature:	

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It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.