



Usability Report

Object: Usability report

Device: Backing layer of cooling gel sheet (or support)

Date: 2024.6.4

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Purpose of this document:

The compatibility of the backing layer (support layer) and peeling layer materials of the cooling patch.

This document summarizes the activities carried out to verify that new products within the new product range do not introduce new risks to their clinical usability.

New product range:

1. Back layer of different materials:

A. Non-woven fabrics

B. Aqueous gel layer

C. Middle mesh cloth

2. Different peeling layers: can be used if they do not react with colloid.

A. PEPET: Material: transparent embossed, white


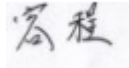
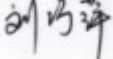
B. PU\TPU material

C. Silicone membrane

Summary

During the usability assessment, newly added materials are analyzed according to the new product range to understand the new risks they may bring in use.

Therefore, changing the availability of different backing materials (or support layers) in practice according to the new product range poses a new risk, as the changes implemented are of low impact and consistent with acceptability in clinical practice.

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Supervision: Liu Qiaoping	Date: 2024-6-4	Signature: 



Topic	PASS/FAIL
Backing layer (support layer)	
<p>The function of the backing layer (or support layer) is to make the peeling strength of the antipyretic patch adhesive greater than that of human skin, and to provide gaps for volatile water, while ensuring that the antipyretic patch adhesive is not easily deformed during production, storage, transportation and use. In actual use, the above three types of materials all achieve these goals, and their ingredients are stable and will not be integrated into the colloid to bring new risks.</p> <p>Therefore, the new backing layer (or support layer) is used in practice to ensure the clinical use purpose of the fever patch and will not bring new risks.</p>	PASS
Different peeling layers	
<p>The role of the peeling layer is to protect the colloid and to enable easy peeling during use. At the same time, the components of the material cannot enter the colloid to bring new risks.</p> <p>The materials currently used are all conventional medical materials and only play the role of bonding and protecting the colloid.</p> <p>Therefore, the use of relevant materials and peeling layers of different thicknesses will not affect the clinical use purpose of the cooling patch and will not bring new risks.</p>	PASS