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To whom it may concern,

17/MARCH/2023

This correspondence is to affirm the safety and components of the Super Patch Company's patches.

Our patches are made with a single-sided medical tape from 3M consisting of a 5-mil transparent polyethylene backing with a matte finish, coated with a medical grade, hypoallergenic pressure-sensitive acrylic adhesive.

The back of the non-permeable tape is printed with a skin-approved ink and die cut while it is still on its liner in an FDA-regulated medical device manufacturing facility. The die-cutting and packaging are performed in a cleanroom. No additives or supplements of any kind are introduced into the patches.

Please see the addendums from our manufacturer Innovize and 3M as to the components and contents of the patches.

The Super Patch Company Ltd LLC is registered with the FDA as an exempt Class 1 Medical Device.

Yours Truly,

Yasmeen Dhaliwal

General Counsel
The Super Patch Company



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Establishment:

THE SUPER PATCH COMPANY LTD LLC
2719 Hollywood Blvd., Suite B-260
Hollywood, FL 33020

Registration Number: 3026035851

FEI Number*: 3026035851

Status: Active

Date Of Registration Status: 2023

Owner/Operator:

[THE SUPER PATCH COMPANY LTD LLC](#)⁶

2719 Hollywood Blvd., Suite B-260
Hollywood, FL US 33020

Owner/Operator Number: [10087033](#)⁷

Official Correspondent:

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Addendum 1:

Letter from Innovize

3-17-23

This single sided medical tape from 3M consists of a 5-mil transparent polyethylene backing with a matte finish, coated with a medical grade, hypoallergenic pressure sensitive acrylic adhesive.

The back of the non-permeable tape is printed with a skin approved ink and die cut while it is still on it's liner in an FDA regulated medical device manufacturing facility. The die cutting and packaging is performed in a cleanroom. No additives or supplements of any kind are introduced into the patch.

Biocompatibility studies of the adhesive are available.

Katy Trudeau
National Sales Manager
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Addendum 2:

Product Clinical Data Summary for
3M Single Coated Medical
Polyethylene Tape



PRODUCT CLINICAL DATA SUMMARY
NO. 1521
3M™ Single Coated Medical Polyethylene Tape
Effective: June 2017
Page 1 of 2

The adhesive used on No 1521, as part of a different construction, has been subjected to the following safety evaluations:

***In Vitro* Cytotoxicity**

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO₂ for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application. There was very slight to well-defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.8. The response of the test article was categorized as slight.

**PRODUCT CLINICAL DATA SUMMARY
NO. 1521
3M™ Single Coated Medical Polyethylene Tape
Effective: June 2017
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Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

3M Study # 05-011343 (all)

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.