



PROTESCO

«УТВЕРЖДАЮ»

АО «ПРОТЕКО»

Чекова Е.С.

по Доверенности № 78 АВ 5341909 от 26.06.2024 г.

«09» октября 2024 г.



Фотографические изображения общего вида медицинского изделия

Материал стоматологический для пломбировки Healtex®

(наименование медицинского изделия)

Материал стоматологический для пломбировки Healtex® HealE-Temp в составе:

- материал стоматологический для пломбировки Healtex® HealE-Temp в контейнере 30 г – 1 шт.;
- инструкция – 1 шт.



Материал стоматологический для пломбировки
Healtex HealE-Temp в контейнере 30 г
LOT ET2104271
26.04.2023

DiaDent®**e-Temp™**

CE 0197

Hydraulic Temporary Restorative

Product

Temporary filling material for standard cavities and post-endodontic treatments

Composition

- ◆ Vinyl resin
- ◆ Zinc oxide
- ◆ Calcium sulfate
- etc.

Indication

- Temporary restorations, especially inlay preparations.
- Temporary fillings and sealing.
- Temporary fillings of implant sites.

Directions for Use

- 1) Isolate the site with rubber dam.
 - 2) Clean and dry the cavity.
 - 3) Use an appropriate instrument to apply the required quantity into the cavity.
 - 4) Complete and compact the filling. In the case of occlusal cavity, check the site after confirming the occlusion.
 - 5) Check the occlusion and remove excess material on the surface with an appropriate instrument.
 - 6) e-Temp should be applied and layered in small quantity until the filling reaches the height of the tooth enamel.
 - 7) e-Temp will harden within 35 minutes after absorption of moisture and saliva in the mouth. Avoid any exposure to shearing pressure for about 2 hours after application.
 - 8) Wait a few minutes until the material is dry. Check to see if the product is well-attached to the tooth using a dental instrument.
- If it has not completely hardened yet, the dental instrument would penetrate the surface of the filled tooth.
- In some cases, where there is a foreign object between the tooth and the material or if the inside of the tooth is not cleaned properly, the material may fall off.

Note

1. Do not mix or use outside the product with any other material.
2. When removing the filling, clean the cavity with an alcohol soaked cotton pellet.

Storage

- 1) Due to sensitivity to moisture, close the jar immediately after use.
- 2) Avoid direct sunlight.
- 3) Store the product in a place at room temperature.
- 4) Shelf Life: 2 years.

Caution

- 1) For use only by a dental professional under the intended indications.
- 2) Do not use on patient who shows signs of allergy or infection.
- 3) Avoid direct contact with running water and consult with physicians.
- 4) Do not use after the shelf life.
- 5) Avoid contact with water or moisture.
- 6) e-Temp can't be polymerized by curing lights.
- 7) Patient care / Maintenance after temporary restoration: e-Temp can remain inside the tooth for up to 2 days. The material may detach itself from the tooth. If the product falls out consult a dentist or a professional dental practitioner immediately.

Contraindication

Very rarely, it can cause hypersensitivity to some patient, in which case discontinue use immediately.

Packages**e-Temp™ Kit (30g) white (2004-1001)****e-Temp™ Kit (10g) white (2005-1011)****Symbols****RX
Only****For Dental Professional Use Only****Warranty and Limitation of Liability**

DiaDent Group International will replace product that is proven to be defective. DiaDent Group International does not accept liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

Contact Information

DiaDent Group International
M. Doudoukian, Managing Director
Chengdu, China
Tel: 86-41-666-2315
Fax: 86-41-666-2658
www.dia-dent.com
dia-dent@dia-dent.com

DiaDent Group International Inc.
11-8871 North Front Way, Burnaby,
B.C. Canada V5J 5Y6
Tel: 1-604-431-0851
Fax: 1-604-431-0855
www.dia-dent.com
dia-dent@dia-dent.com

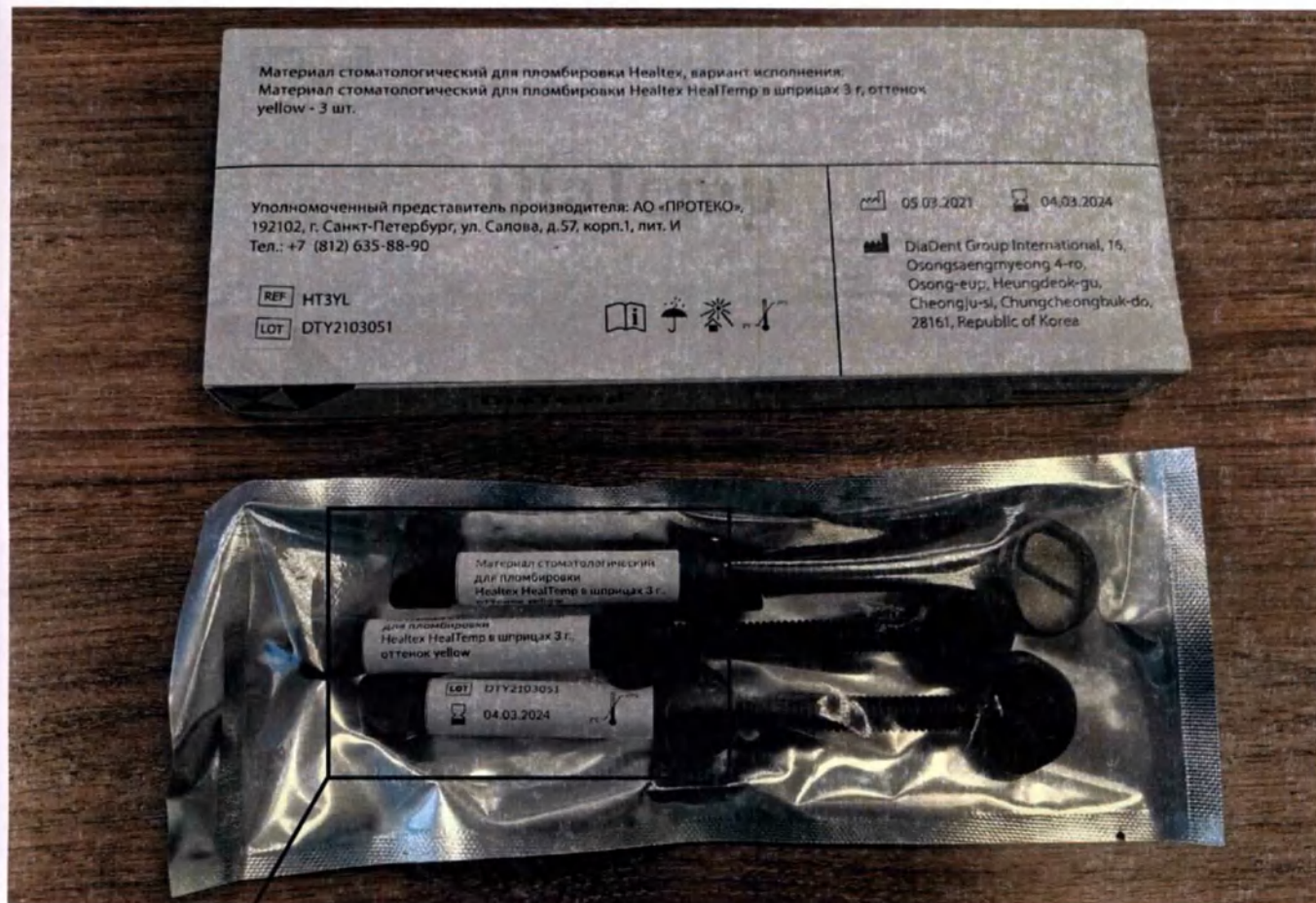
DiaDent Europe B.V.
Aankomstweg 10, 3322 AS
Almere, The Netherlands
Tel: 31-36-549-8607
Fax: 31-36-536-7317
www.dia-dent-europe.com
dia-dent@dia-dent-europe.com

EC REPDIA DENT GROUP
EUROPEAN REPRESENTATIVE
Tel: 31-36-549-8607

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Материал стоматологический для пломбировки Healtex® HealTemp, оттенок yellow в составе:

- материал стоматологический для пломбировки Healtex® HealTemp в шприцах 3 г, оттенок yellow - 3 шт.;
- инструкция- 1 шт.



материал стоматологический для пломбировки Healtex HealTemp в шприцах 3 г, оттенок yellow

LOT DTY2103051
04.03.2024

DiaDent®**DiaTemp™**

CE 0197

Light-Cured Temporary Filling Material

Product

DiaTemp™ is a temporary filling material that sets with curing light. In case the cavity is not permanently restored, DiaTemp™ can be used as a temporary restoration until the next appointment.

Indication

1. Temporary filler that can be applied on both inlay and onlay.
2. Has excellent elasticity and surface hardness, shows excellent masticatory force.
3. Adhesion with teeth is excellent and can be easily removed.
4. Does not require additional mixing and can be used directly from the pre-filled syringe.

Preparation before Use

1. Before use, please double check the expiration date, presence of foreign substances, impurities and the deterioration (stiffen materials is prohibited to use).
2. It is strongly recommended that the operator read the instructions carefully prior to using the DiaTemp™.
3. Prepare all necessary accessories for the procedure in advance.
4. Apply a rubber dam to the patient.

Usage

1. Wash and dry the prepared tooth cavity to be filled.
2. Choose appropriate size of spatula, fill the cavity with DiaTemp™ and make sure that there are no gaps in between for hermetic seal.
3. After filling the cavity, check occlusion of the teeth and adjust the excess filling as needed for a perfect bite.
4. Using a curing light such as D-Lux+, irradiate light with a light intensity of 500 mW/cm² for 20-30 seconds vertically within 2mm distance. If the light intensity of the used during light device is less than 500 mW/cm², the light irradiation time can be added for perfect curing.
5. Close the lid of DiaTemp™ and store the product aside.

Removal

1. Check the tooth cavity to be removed.
2. Remove cured DiaTemp™ with suitable instrument. The product should come off easily in one try.
3. Remove any residual of cured material from the tooth cavity.

How to store and manage after use

1. After use, or soon to replace the lid.
2. Avoid direct sun light and excessive heat. Store in dry place at room temperature.
3. Do not store near fire.
4. Keep out of reach of children.
5. Do not change the product container arbitrarily.

Caution

1. This product is strictly prohibited by use of non-professional users. DiaTemp™ is to be used for dental purpose only.
2. It should be used by dental professionals and should be used in accordance with usage instructions and precautions for use.
3. After opening, close the syringe cap immediately to prevent hardening by natural light.
4. Do not use product after its expiry date.
5. Wear protective gloves when handling the product.
6. During use, be careful not to come in direct contact with skin or eyes. If contact is made, discontinue use and flush with running water immediately, and consult with an expert.
7. Do not use on patients with inflammation or a lesion to this product.
8. This product should not be prescribed for internal use.
9. Use as soon as possible after opening.
10. Avoid contact with water.
11. This filling remains in the body for 29 days or LESS.

Application Notes

1. Do not apply heat to the product.
2. Do not mix with other products.

Packages

DiaTemp™ 3g x 3 syringes kit (A2003-1101) : BLUE
DiaTemp™ 3g x 3 syringes kit (A2003-1201) : YELLOW

Symbols**Warranty and Limitation of Liability**

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European Representative

DiaDent Europe B.V.
Antennestraat 70, 1322AS Almere, The Netherlands
Tel: 31-36-549-8607 FAX: 31-36-536-7317

Contact Information**DiaDent Group International**

16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Chongju-si Chungcheong buk-do, 28161, Korea
Tel: 82-43-266-2315
Fax: 82-43-262-8658
www.diaident.co.kr
diaident@diaident.co.kr

DiaDent Group International Inc.

11-3871 North Fraser Way, Burnaby,
B.C., Canada, V5J 5G6
Tel: 1-604-451-8851
Fax: 1-604-451-8865
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diaident@diaident.com

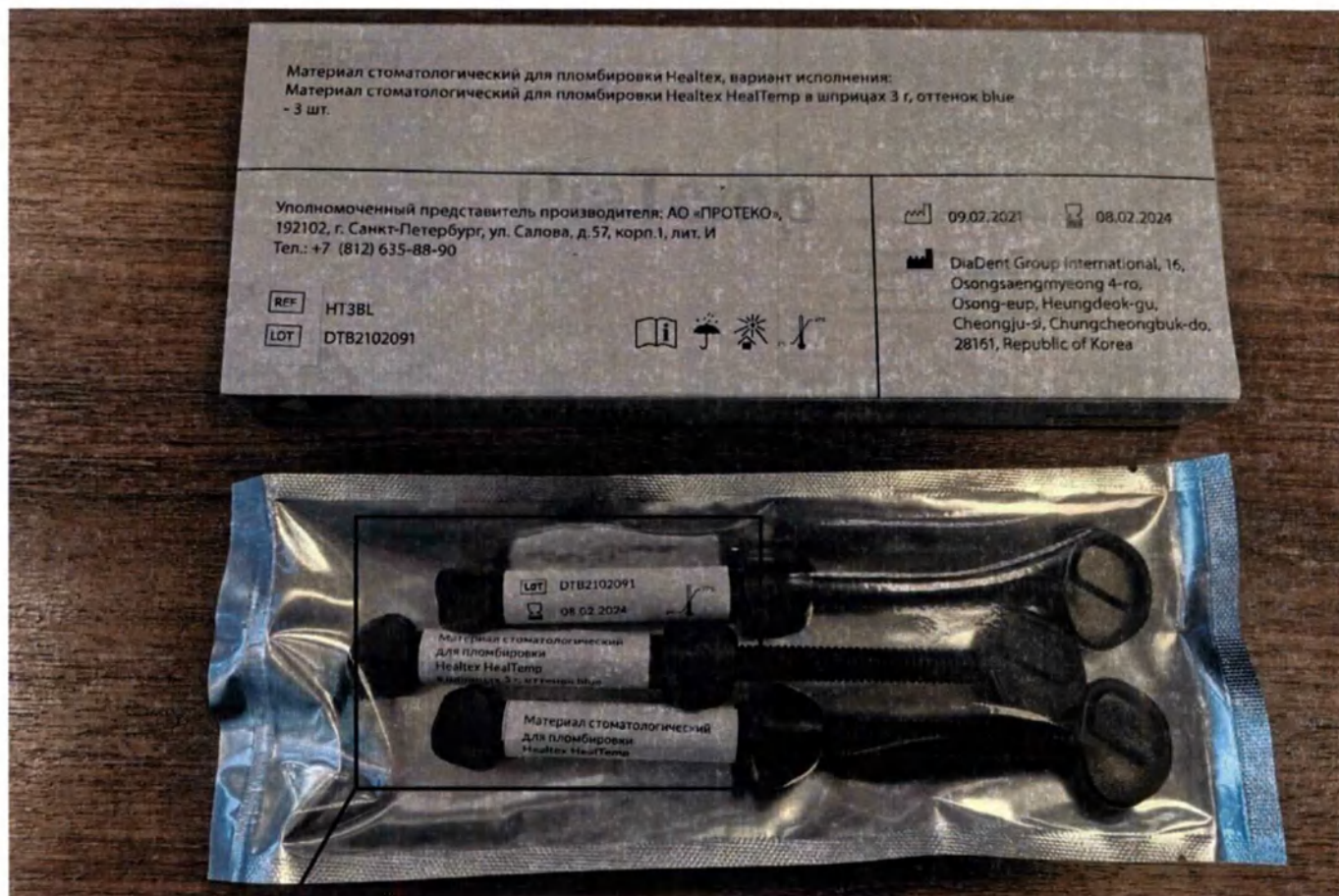
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для пломбировки
Healtex HealTemp
в шприцах 3 г, оттенок blue
LOT DTB2102091
08.02.2024

DiaDent®**DiaTemp™**

CE 0197

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Fax: 82-43-262-8658
www.diaDent.co.kr
diaDent@diaDent.co.kr

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B.C., Canada, V5J 5G6
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Fax: 31-36-536-7317
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diaDent@diaDentEurope.com

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Маркировка первичной упаковки





HEALTEX[®]

3г

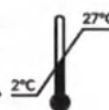
**МАТЕРИАЛ СТОМАТОЛОГИЧЕСКИЙ
для пломбировки Healtex[®] HealTemp**



«DiaDent Group International»

(«Диадент Групп Интернейшнл»)

16, Osongsaengmyeong 4-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chung-
cheongbuk-do, 28161, Republic of Korea

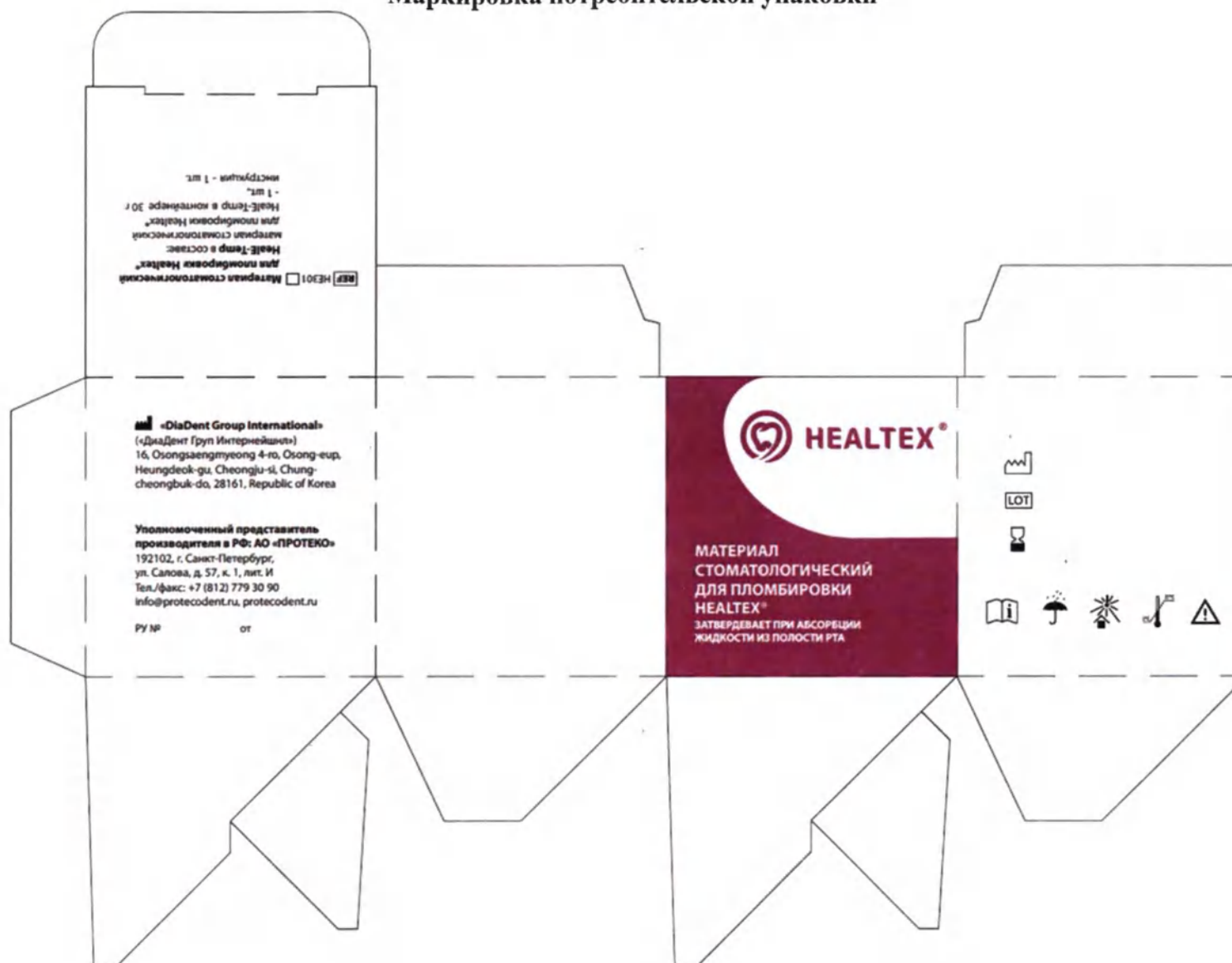


LOT



Yellow

Маркировка потребительской упаковки





Макет стикера для транспортной упаковки



Прошито, пронумеровано и скреплено печатью
12 (двадцать)) листа(ов)
АО «ПРОТЕРО» Чекова Е.С.
на основании Доверенности № 78 АВ 5341909 от 26.06.2024 г.

