

«УТВЕРЖДАЮ»

Генеральный директор ООО «ТС Дентал»



Званская М.В.

"10" июня 2021 г.

ФОТОГРАФИЧЕСКОЕ ИЗОБРАЖЕНИЕ МЕДИЦИНСКОГО ИЗДЕЛИЯ

1

Дозатор стоматологический шприцевой автоматический, варианты
исполнения QuickSleeper и SleeperOne5, производства DENTAL HI TEC
(ДЕНТАЛ ХИ ТЕК), Франция.

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I Дозатор стоматологический шприцевой автоматический QuickSleeper в составе:

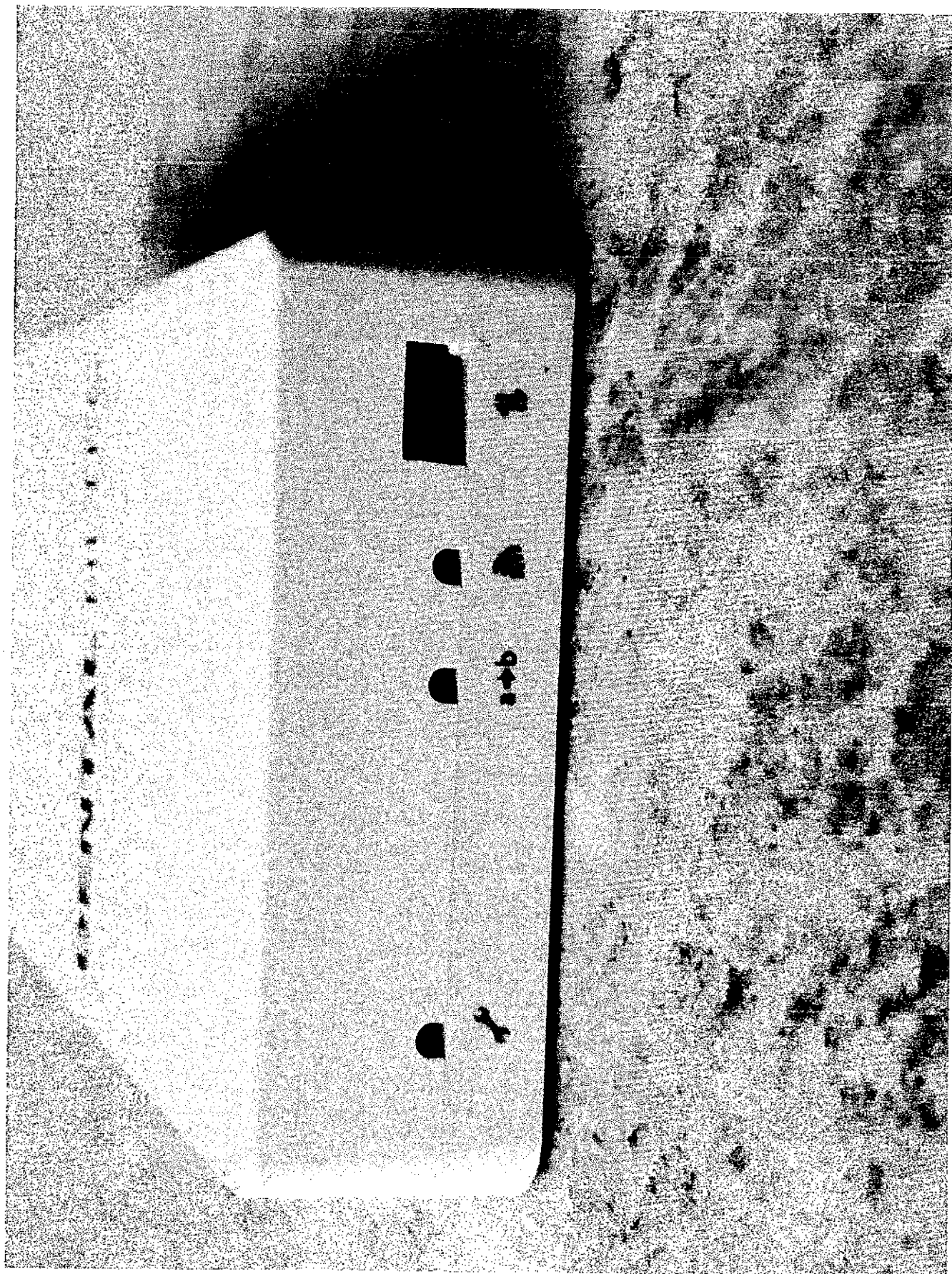


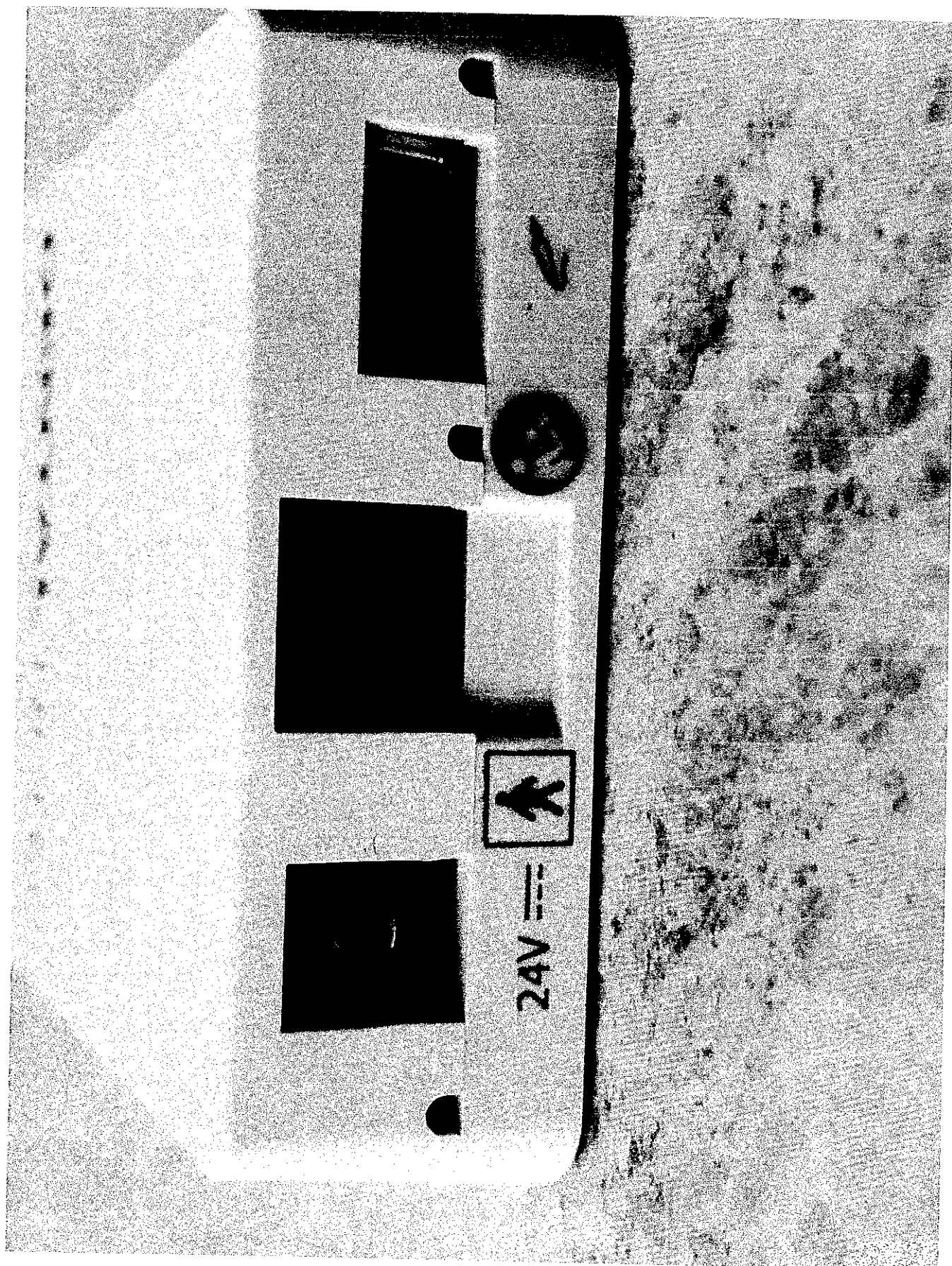


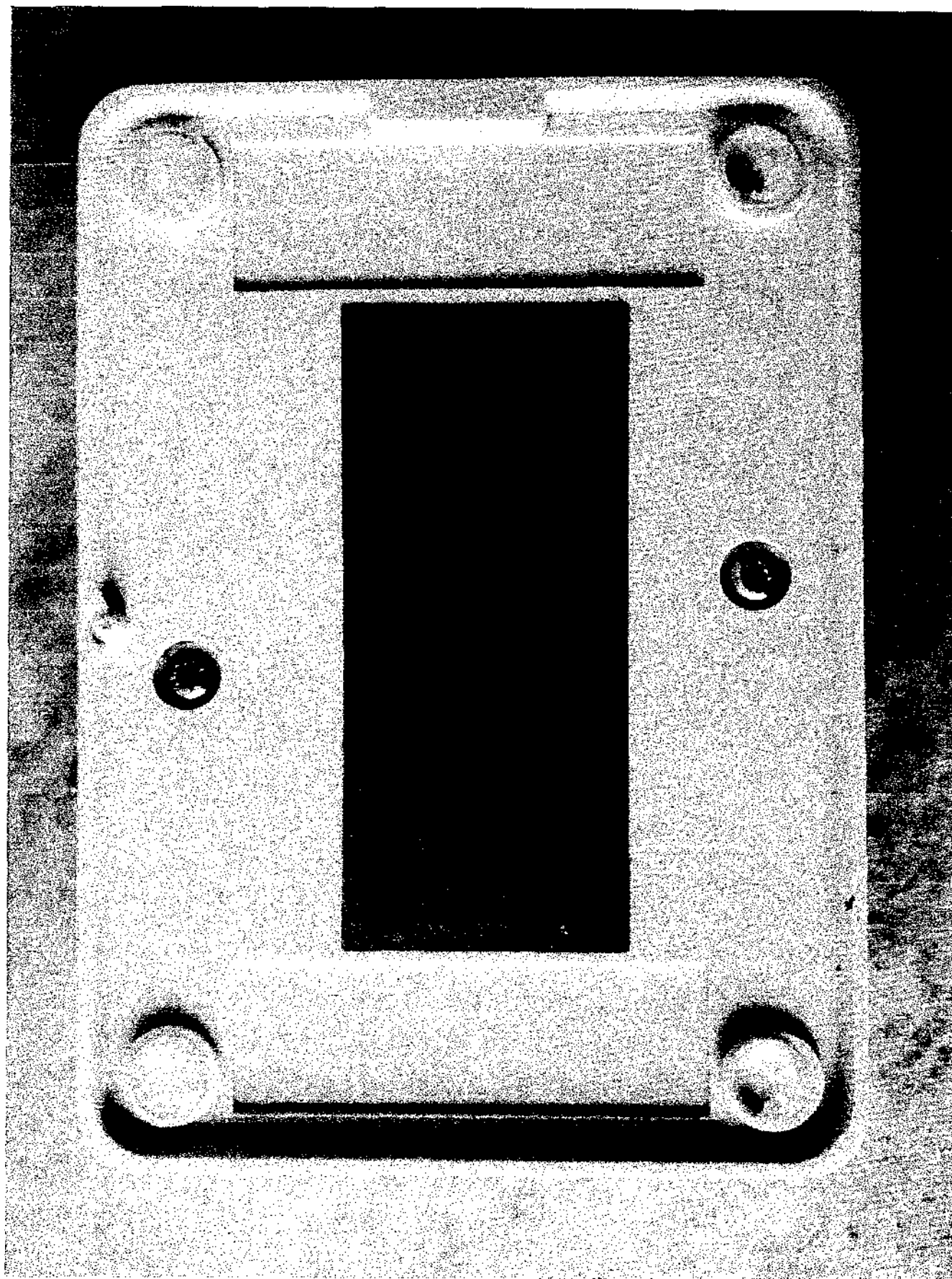




DENTAL HI TEC

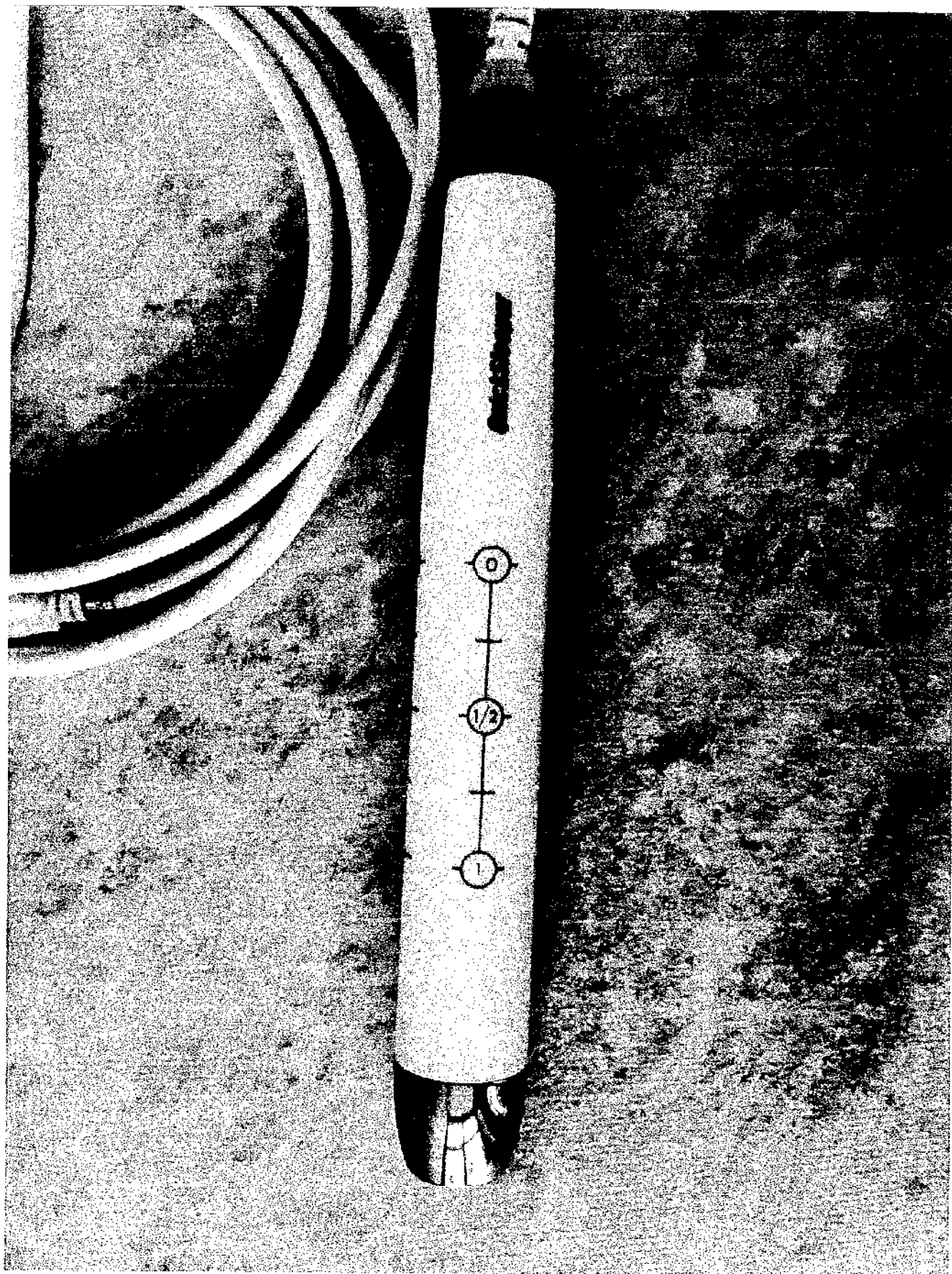


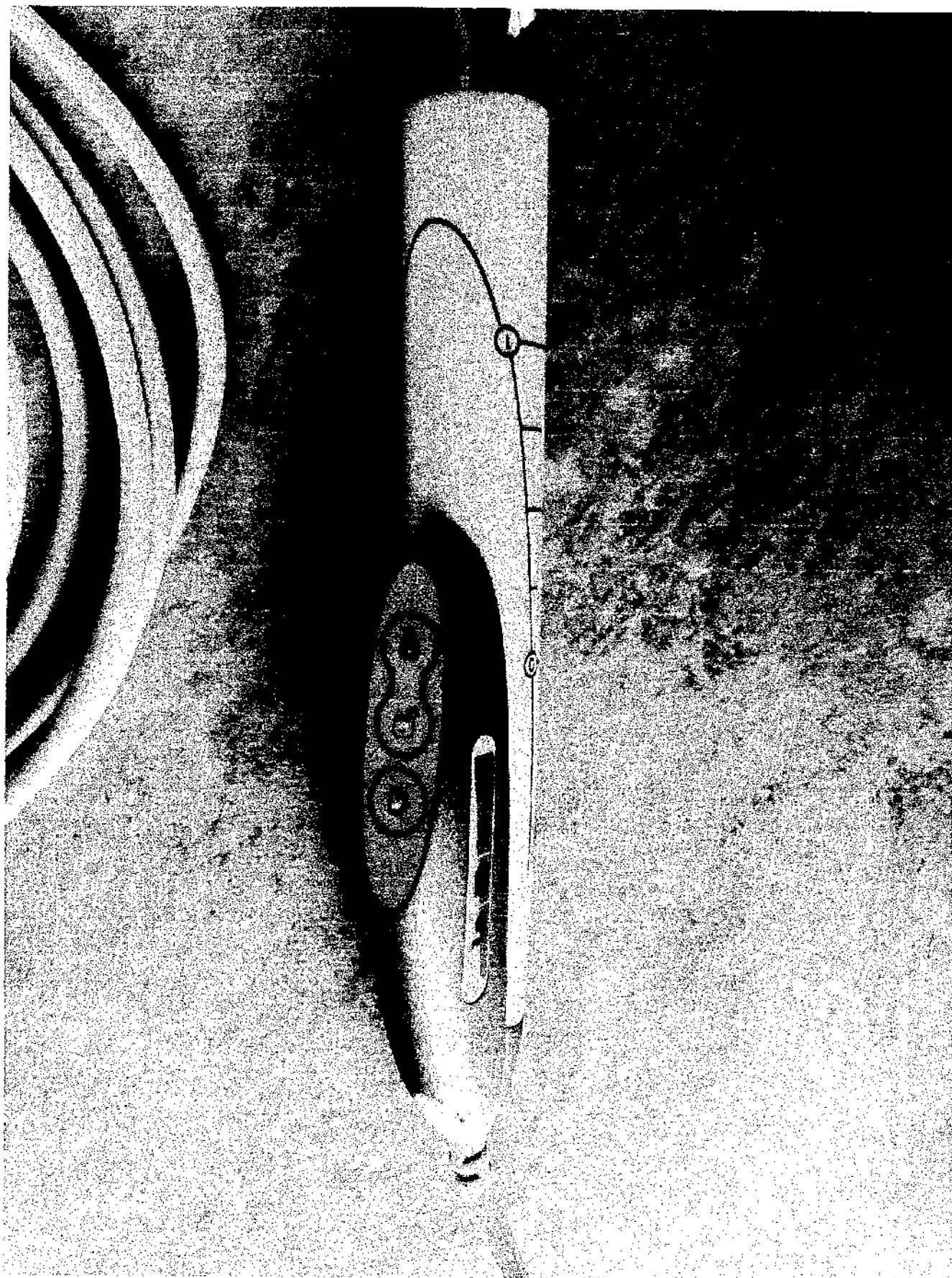




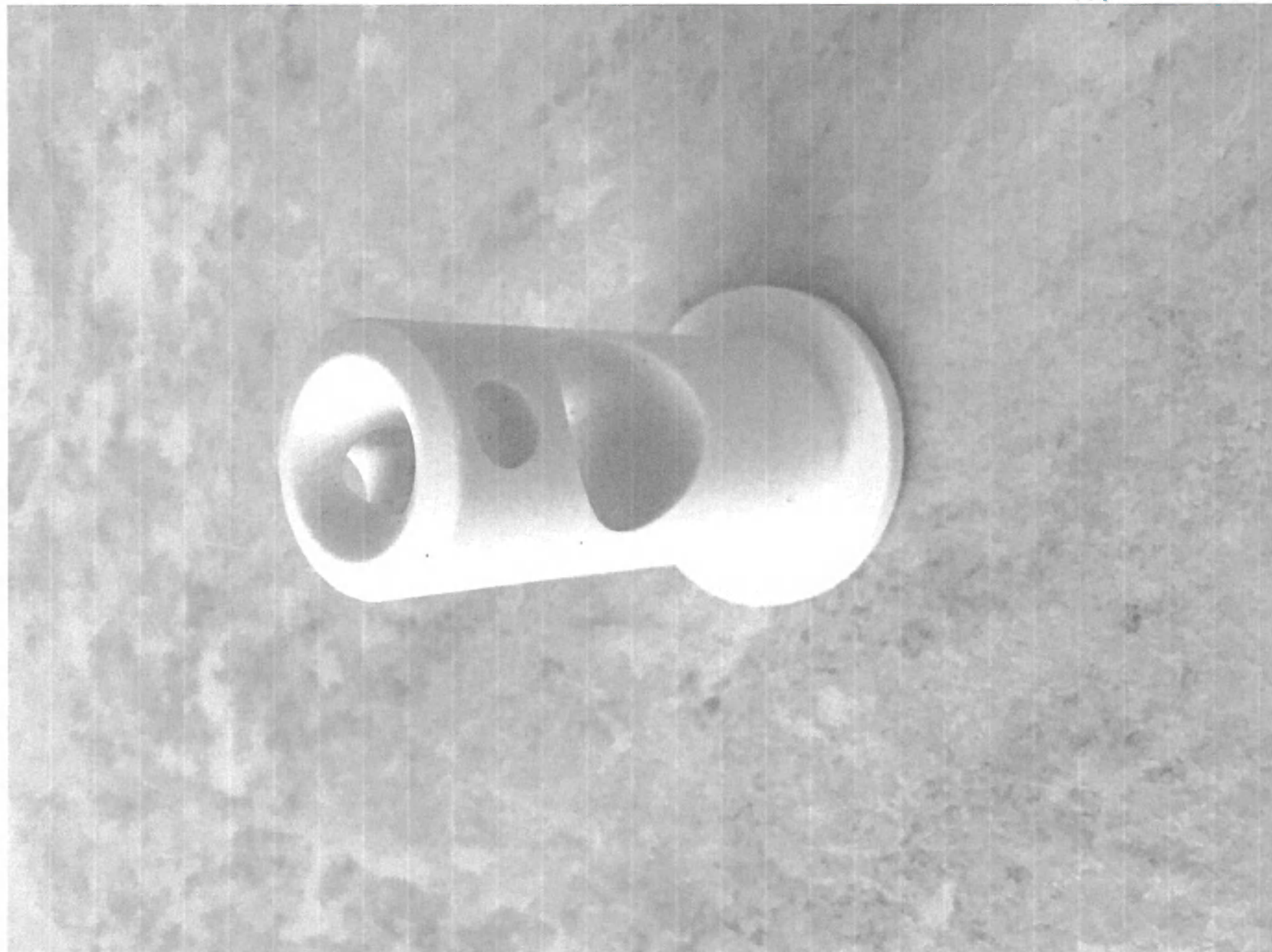
2. Наконечник

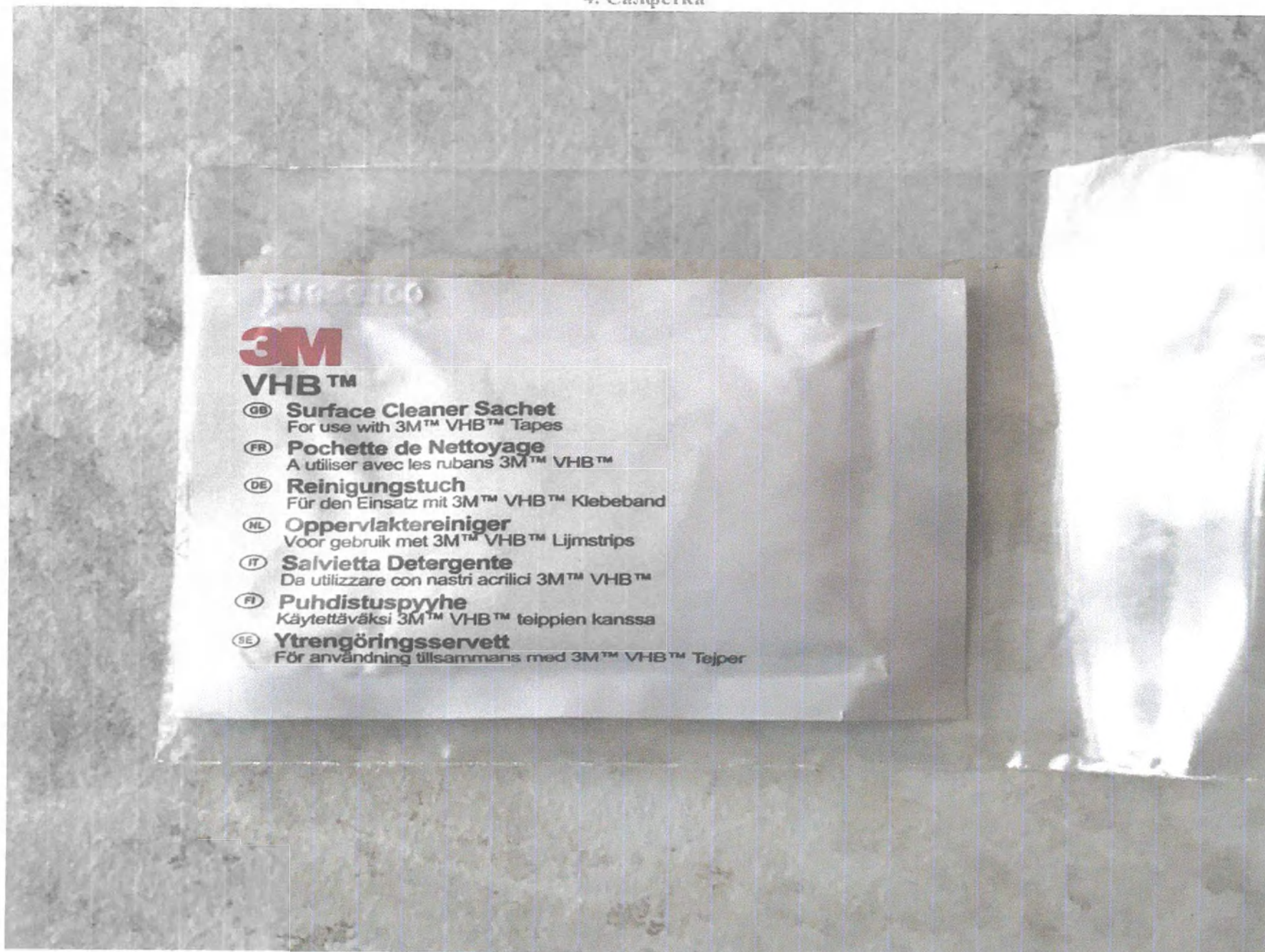






3. Держатель наконечника





5. Беспроводная педаль

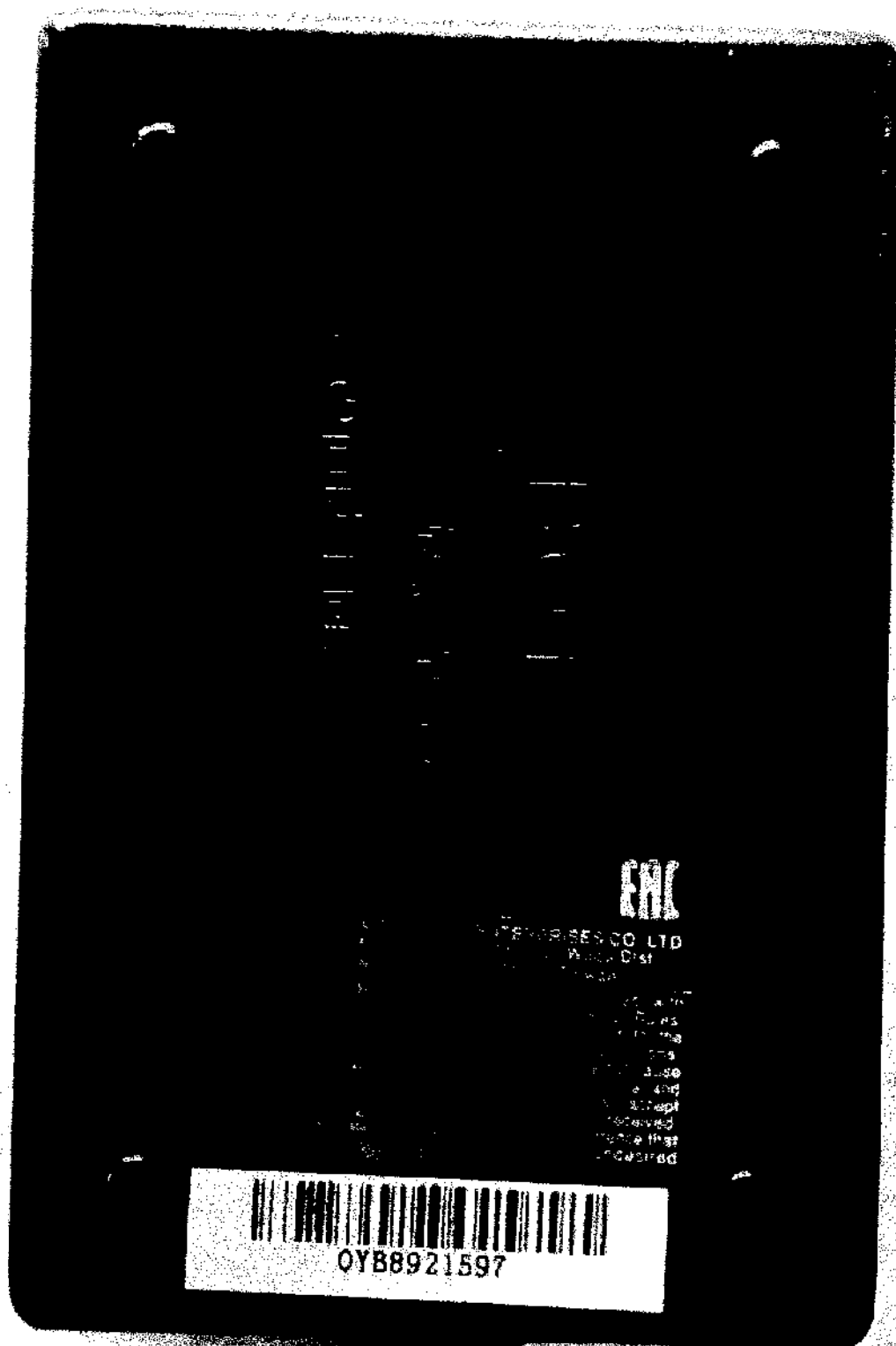


6. Кабель питания

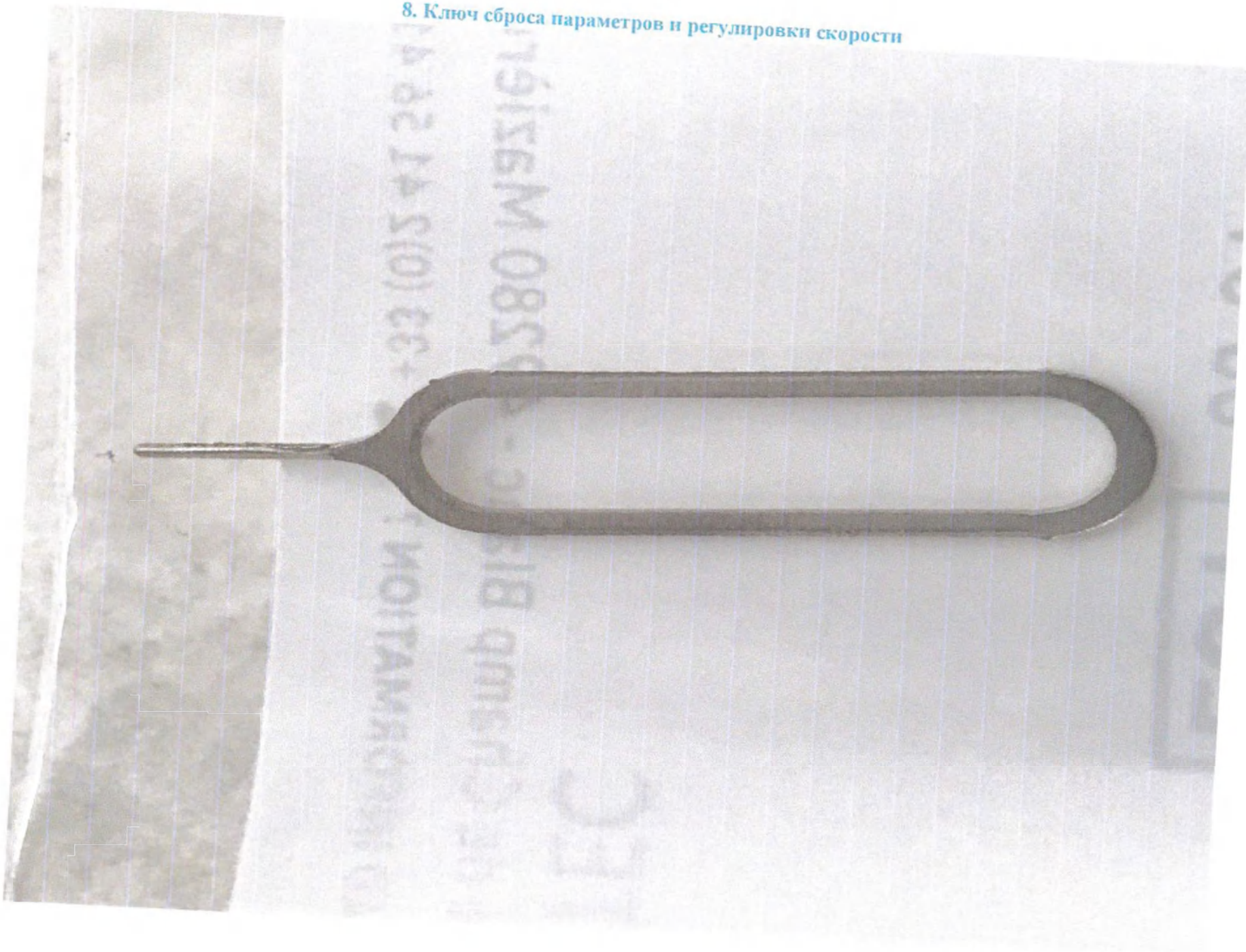


Источник питания 7.





8. Ключ сброса параметров и регулировки скорости



CLÉ D'OPTIONS OPTIONS KEY

REF

SA6785

LOT

00-01



05-2017



DENTALHITEC

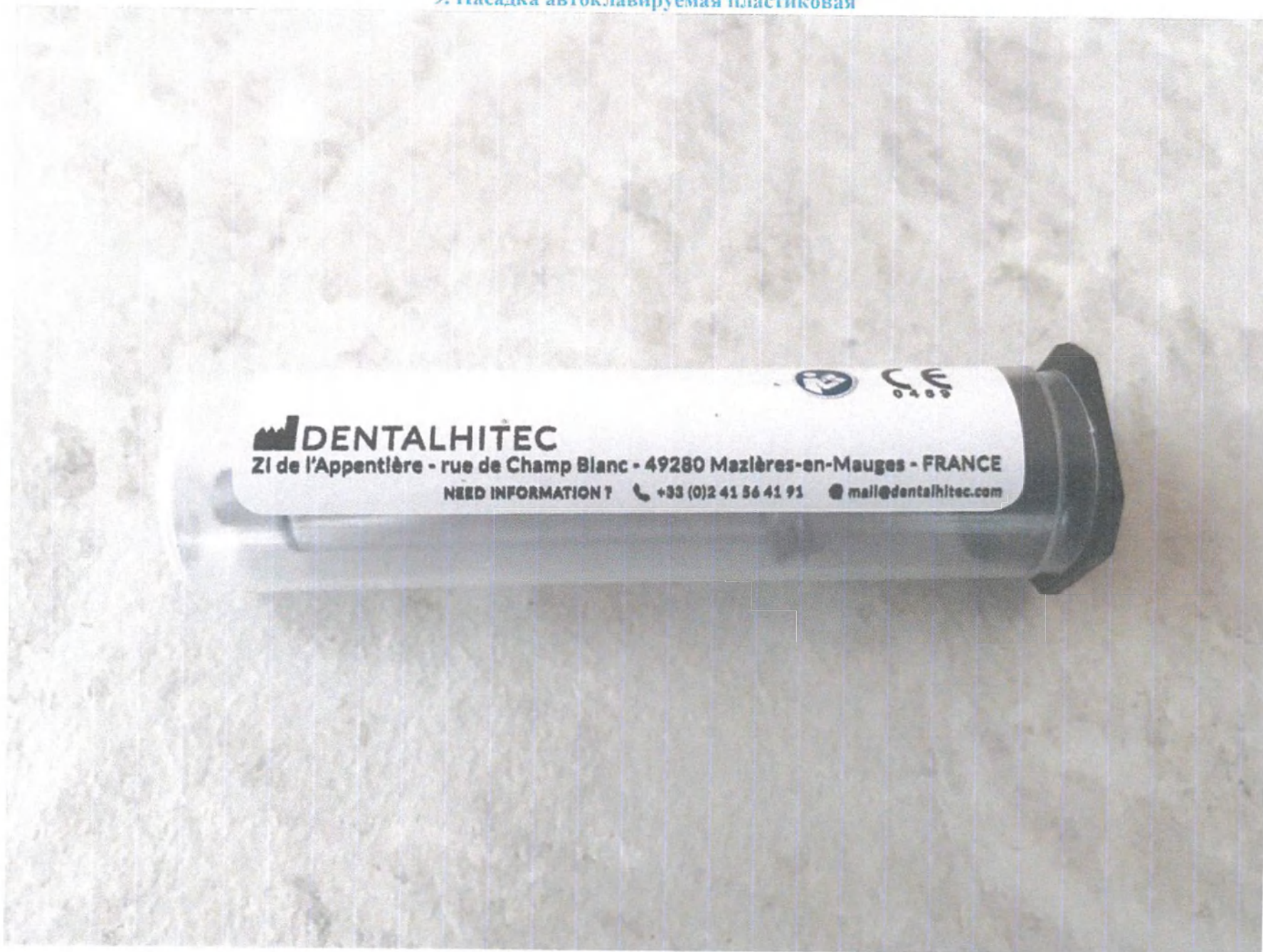
ZI de l'Appentière - rue de Champ Blanc - 49280 Mazières-en-Mauges - FRANCE

NEED INFORMATION ?

☎ +33 (0)2 41 54 41 91

✉ mail@dentahitec.com

9. Насадка автоклавируемая пластиковая





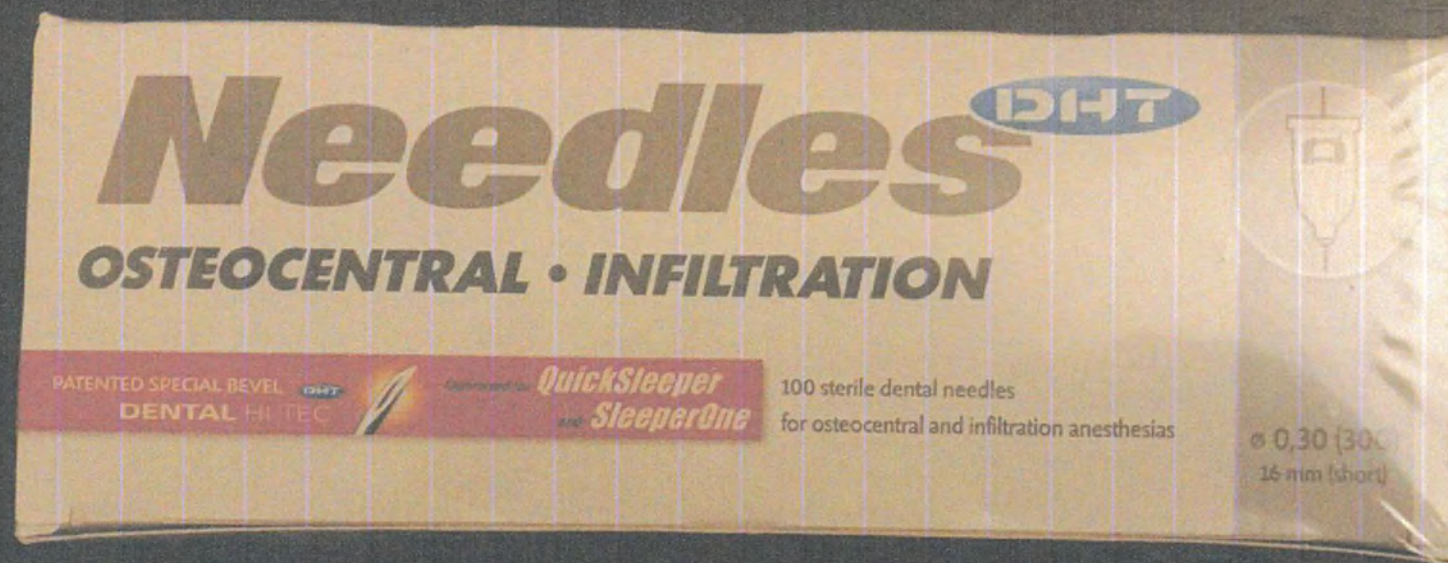
10. Насадка автоклавируемая металлическая – не более 6 шт.





11. Иглы стоматологические стерильные одноразовые (Иглы DHT), стартовый набор:

- игла 30G – 16мм



2023-12
F08172AA

##

STERILE



SOFIC
3 rue Jean-Jacques Rousseau
BP 282 - AUSSILLON
F 81207 MAZAMET CEDEX

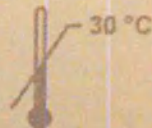
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www.dentalhitec.com

STERILE

For USA : Rx Only
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CE
0086



Ne pas plier l'aiguille avant et après usage.

Do not fold the needle before and after use.

No doblar la aguja antes ni después del uso.

Réservé à l'usage professionnel en médecine bucco-dentaire.

For professional use only in the practice of dentistry.

Producto reservado exclusivamente para el uso del especialista en odontoestomatología.



Voir sous la boîte

See bottom side
of the box.

Ver en la parte
inferior de la caja.



ø 0,30 (30G) - 16 mm (short)

OSTEOCENTRAL • INFILTRATION



Anesthésie en muqueuse attachée
Anesthesia of the attached mucosa
Anestesia de la mucosa adherida

Aiguilles^{DHT}

Aiguilles à usage unique. Ne pas stériliser ou réutiliser.
À conserver dans son emballage d'origine jusqu'à utilisation.
Pour bénéficier de tous les avantages des aiguilles DHT, procédez comme indiqué ci-dessous.
Pour des performances maximales, l'utilisation d'une seringue avec prise stylo (points d'appui) et injection électronique est fortement conseillée.

Veillez à correctement orienter le repère de l'aiguille pour ce type d'anesthésie :

ANESTHÉSIE EN MUQUEUSE ATTACHÉE :

Pour une pénétration indolore même chez l'enfant, orientez le repère à l'opposé de la muqueuse et inclinez l'aiguille pour qu'elle soit presque parallèle à la muqueuse (1).
Enfoncez délicatement le biseau de moins d'un millimètre en injectant très lentement.

Needles^{DHT}

Single use needles. Do not sterilize or reuse.
Store in original packaging until ready to use.
In order to benefit from all of the advantages of the DHT needles, proceed as indicated below.
For maximum performance, the use of a syringe allowing the use of a pen grip (support points) and an electronic injection is highly recommended.

Be sure to correctly orientate the needle indicator for this type of anesthesia:

ANESTHESIA OF THE ATTACHED MUCOSA:

For a pain free penetration even with children, orientate the indicator opposite the mucosa and incline the needle so that it is almost parallel to the mucosa (1). While injecting very slowly, delicately penetrate the bevel by less than a millimeter.

Agujas^{DHT}

Agujas de un solo uso. No reutilizar, reprocesar o reesterilizar.
Consérvesen en el empaque de origen hasta el uso.
Para gozar de todas las ventajas de las agujas DHT, proceda como se indica más abajo.
Para un rendimiento óptimo, la utilización de una jeringa de tipo estilográfico (puntos de apoyo) e inyección electrónica es fuertemente aconsejada.

Asegúrese de orientar correctamente la señal del bisel para este tipo de anestesia :

ANESTESIA DE LA MUCOSA ADHERIDA:

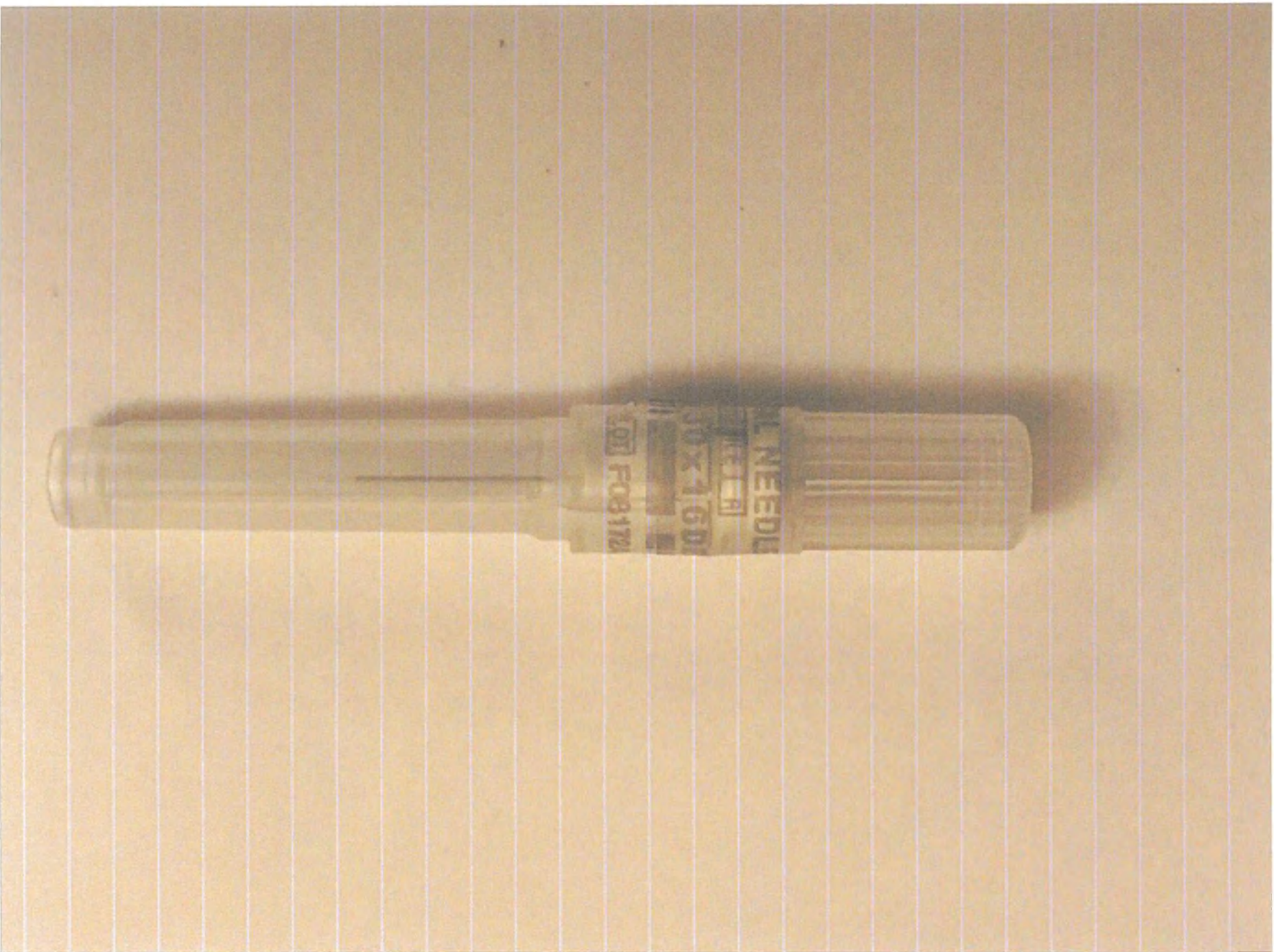
Para una penetración sin dolor incluso para los niños, oriente la señal del bisel **enfrente a la mucosa** y la inclinación de la aguja de manera **casi paralela** a la mucosa (1).
Inserte suavemente el bisel de menos de un milímetro debajo de los tejidos y inyecte el producto anestésico muy lentamente.

Plus d'information sur www.dentahitec.com
(vidéos d'anesthésie avec les aiguilles DHT...)

More information : www.dentahitec.com
(videos with needles DHT...)

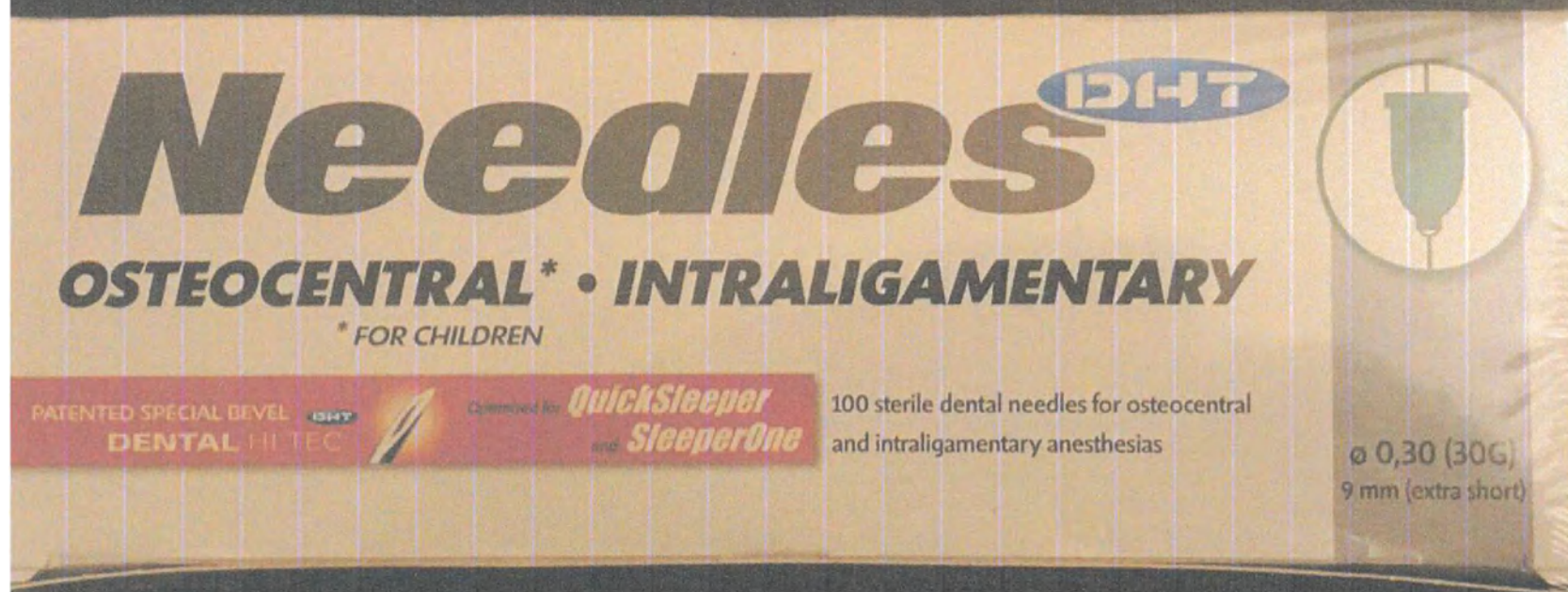
Más información : www.dentahitec.com
(vídeos con agujas DHT...)

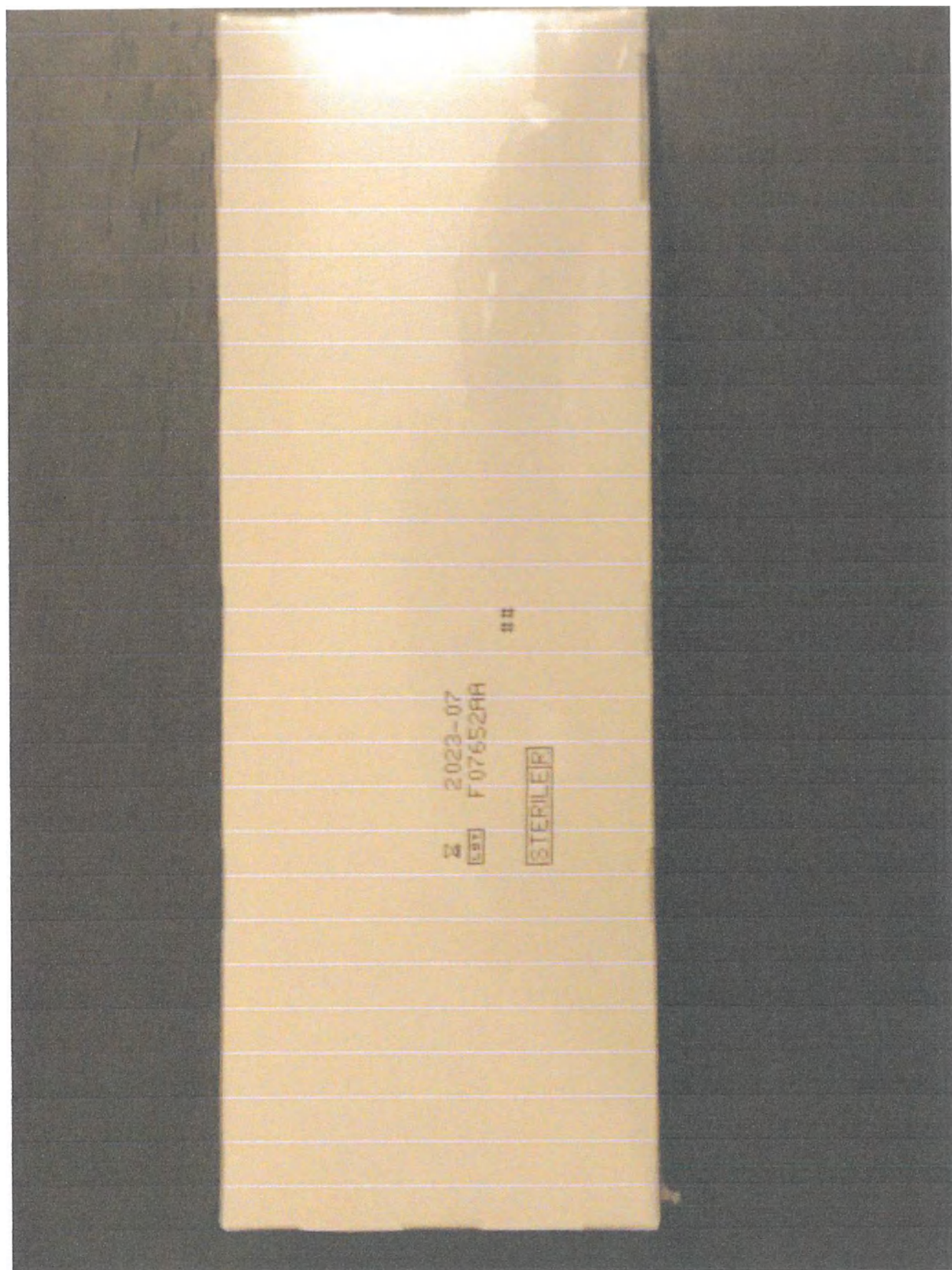






- игла 30G- 9 мм







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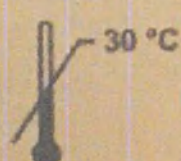
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Ne pas plier l'aiguille avant et après usage.

Do not fold the needle before and after use.

No doblar la aguja antes ni después del uso.

Réservé à l'usage professionnel en médecine bucco-dentaire.

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Voir sous la boîte

See bottom side
of the box.

Ver en la parte
inferior de la caja



ø 0,30 (30G) - 9 mm (extra short)

OSTEOCENTRAL* • INTRALIGAMENTARY

* FOR CHILDREN





DENTAL HI TEC

ZI de l'appentière - 49280 MAZIERES-EN-MAUGES - FRANCE

www.dentalhitec.com

Aiguilles^{DHT}
Needles^{DHT}
Agujas^{DHT}



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CEDEX - FRANCE



0086



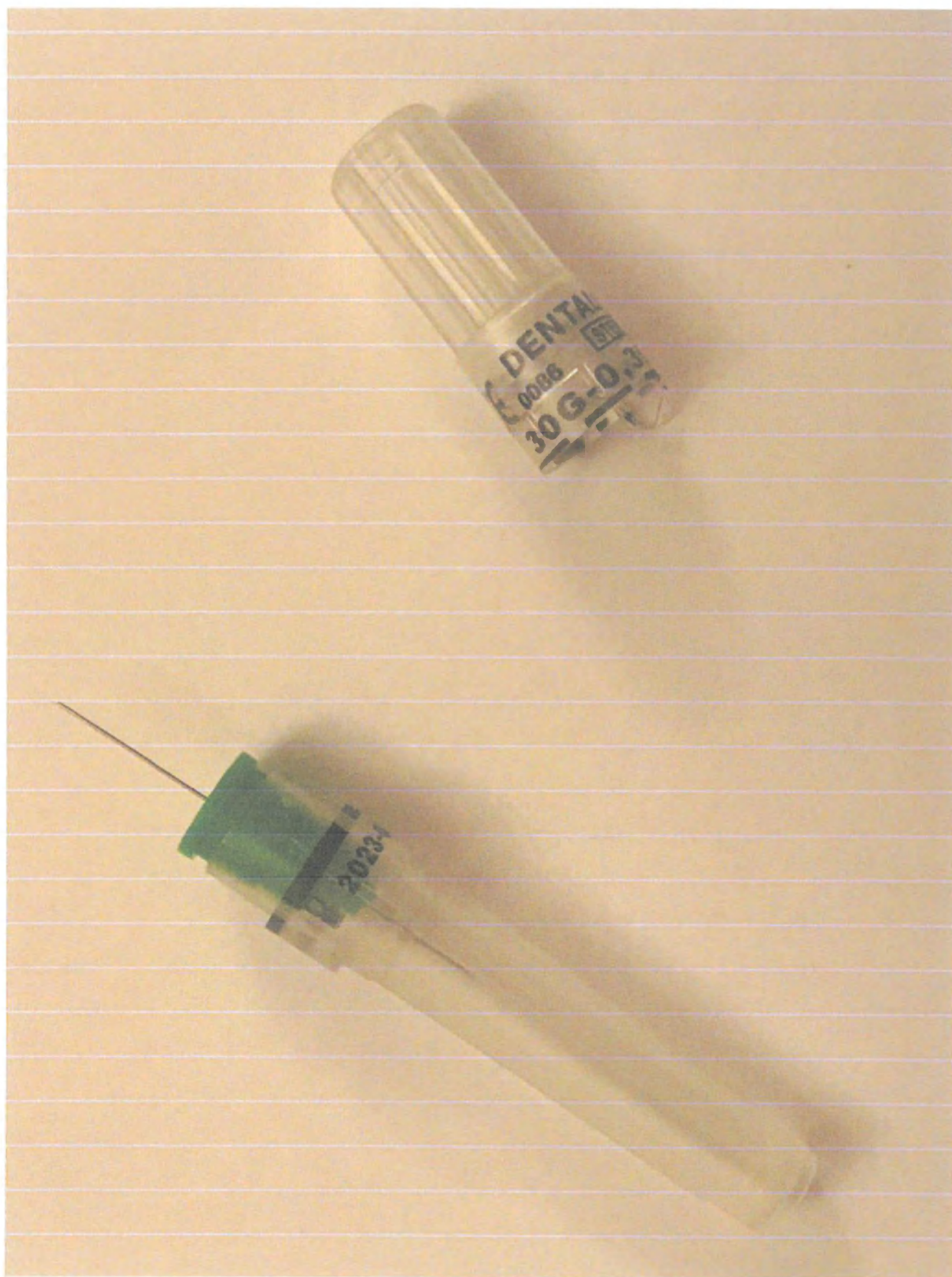
30°C

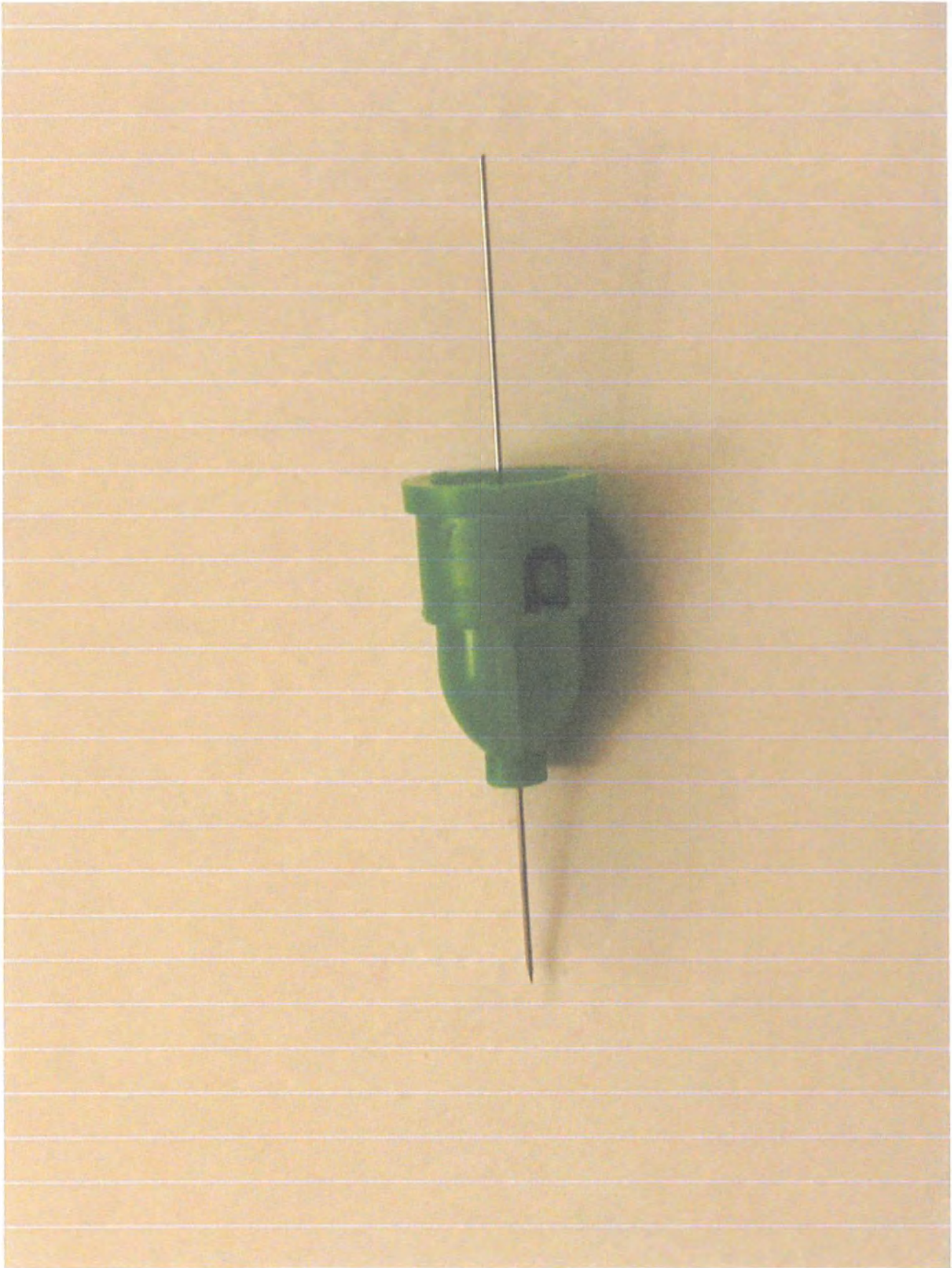


STERILE

PRODHT/10/12-V4 IP







- игла 27G – 16мм



2023-12

LBT F08166AA
STERILE

Ne pas plier l'aiguille avant et après usage.

Do not fold the needle before and after use.

No doblar la aguja antes ni después del uso.

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For professional use only in the practice of dentistry.

Producto reservado exclusivamente para el uso del especialista en odontostomatología.



Voir sous la boîte.

See bottom side of the box.

Ver en la parte inferior de la caja.



ø 0,40 (27G) - 16 mm (short)

TRANCORTICAL • OSTEOCENTRAL



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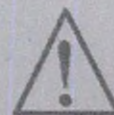
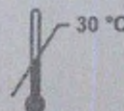
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QuickSleeper

РУКОВОДСТВО ПОЛЬЗОВАТЕЛЯ



Версия QSS-16102019 UK

DENTAL HI TEC

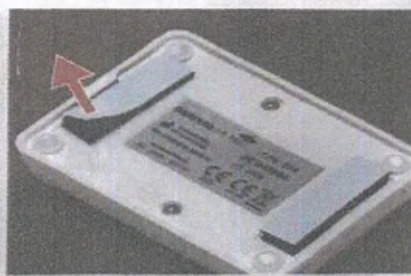
15, rue de la Dent, 67000 Strasbourg, France

Ref. SA0226

Adhesive Strips

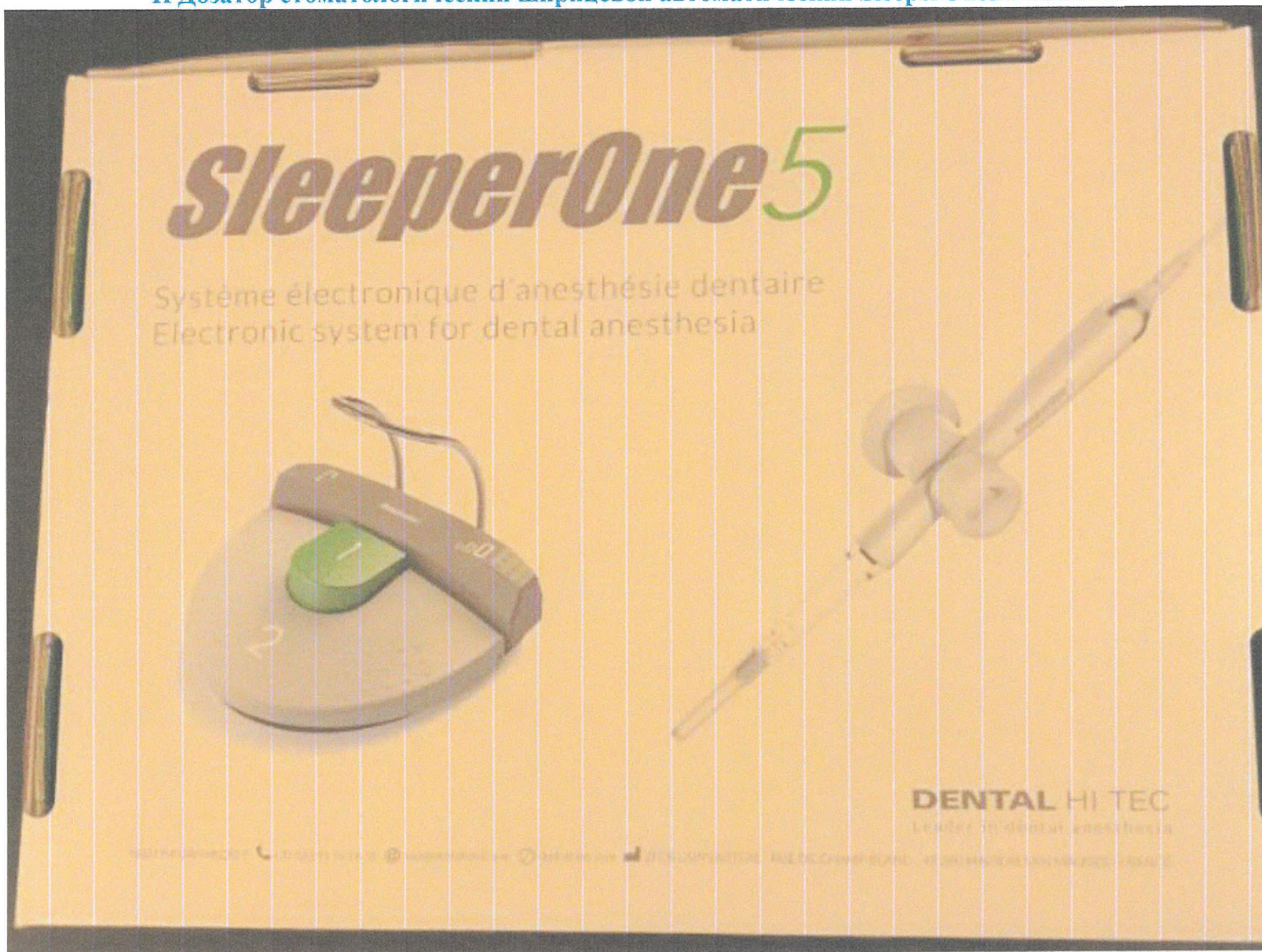
Adhesive strips to fix your DHT electronic control box.
Fit the adhesive strips as indicated. It is recommended to wait a minimum of 2 hours before unclipping the unit in order to prevent the adhesives from becoming unstuck. The fixation will be optimal after 12 hours. This fixation system allows you to clip/unclip the control box at will.

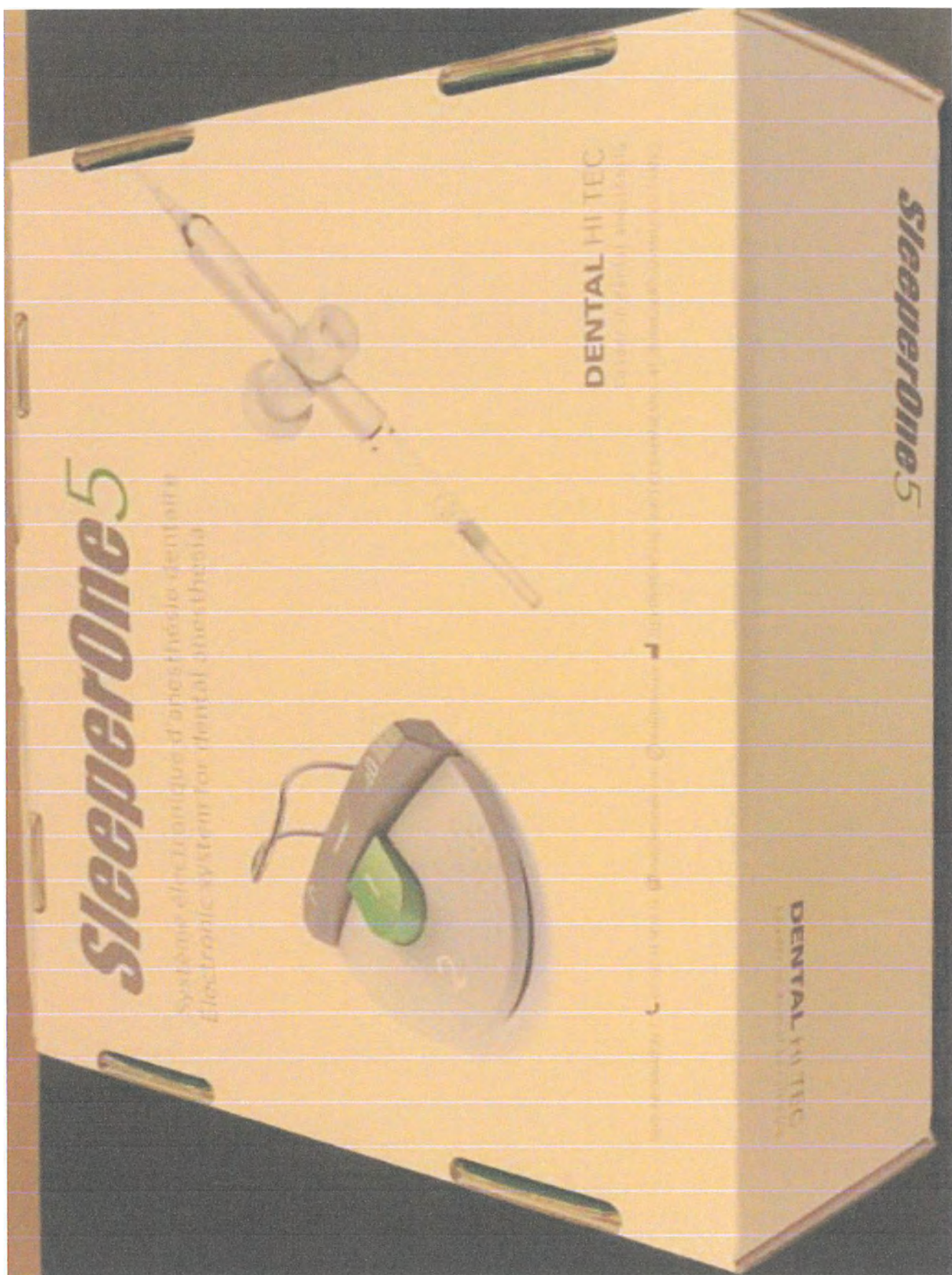
DHT
DENTAL HI TEC





II Дозатор стоматологический шприцевой автоматический SleeperOne5 в составе:





www.dentalhitec.com

REF 55.1B SN 55B00878
2018

Altitude < 3000 m
15% 30% 40%
1000HP 2000HP 3000HP

CONDITIONS DE STOCKAGE
STORAGE CONDITIONS

10% 15% 20% 30% 40%
1000HP 2000HP 3000HP

CONDITIONS DE TRANSPORT
TRANSPORT CONDITIONS



- 1 Accompanying documentation
- 1 Set of disposables is available upon the country
- 1 Power supply cord
- 1 Power supply
- 1 Option key
- 1 Set of sterilizable accessories
- 1 Handpiece holder
- 1 Pedal hoop
- 1 Wireless foot pedal
- 1 Handpiece and control box

ITEMS OF THE BOX

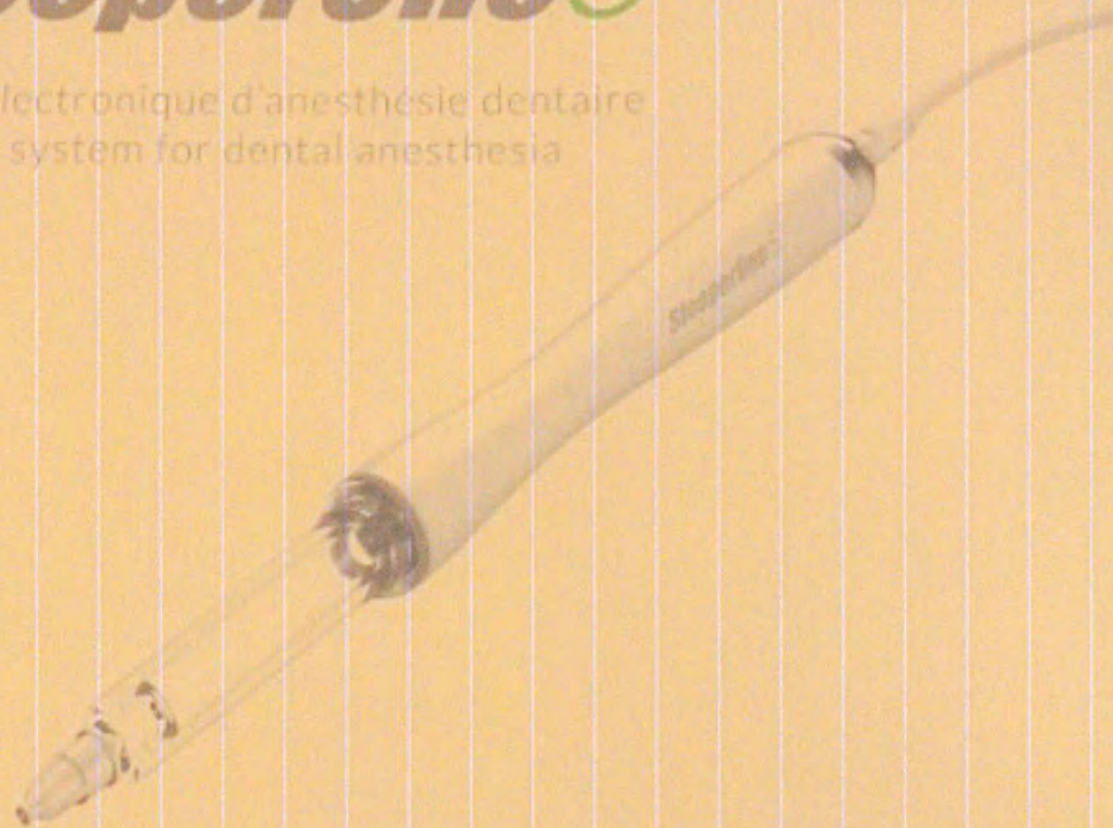
- 1 Documentation d'accompagnement
- 1 Lot de consommables disponible selon les pays
- 1 Cordon secteur
- 1 Bloc d'alimentation
- 1 Clé d'option
- 1 Lot d'accessoires stérilisables
- 1 Support de pièce à main
- 1 Arcueil de pédale
- 1 Pédale sans fil
- 1 Pièce à main et boîtier de contrôle

CONTENU DU COFFRET

Sleepers 5

SleeperOne5

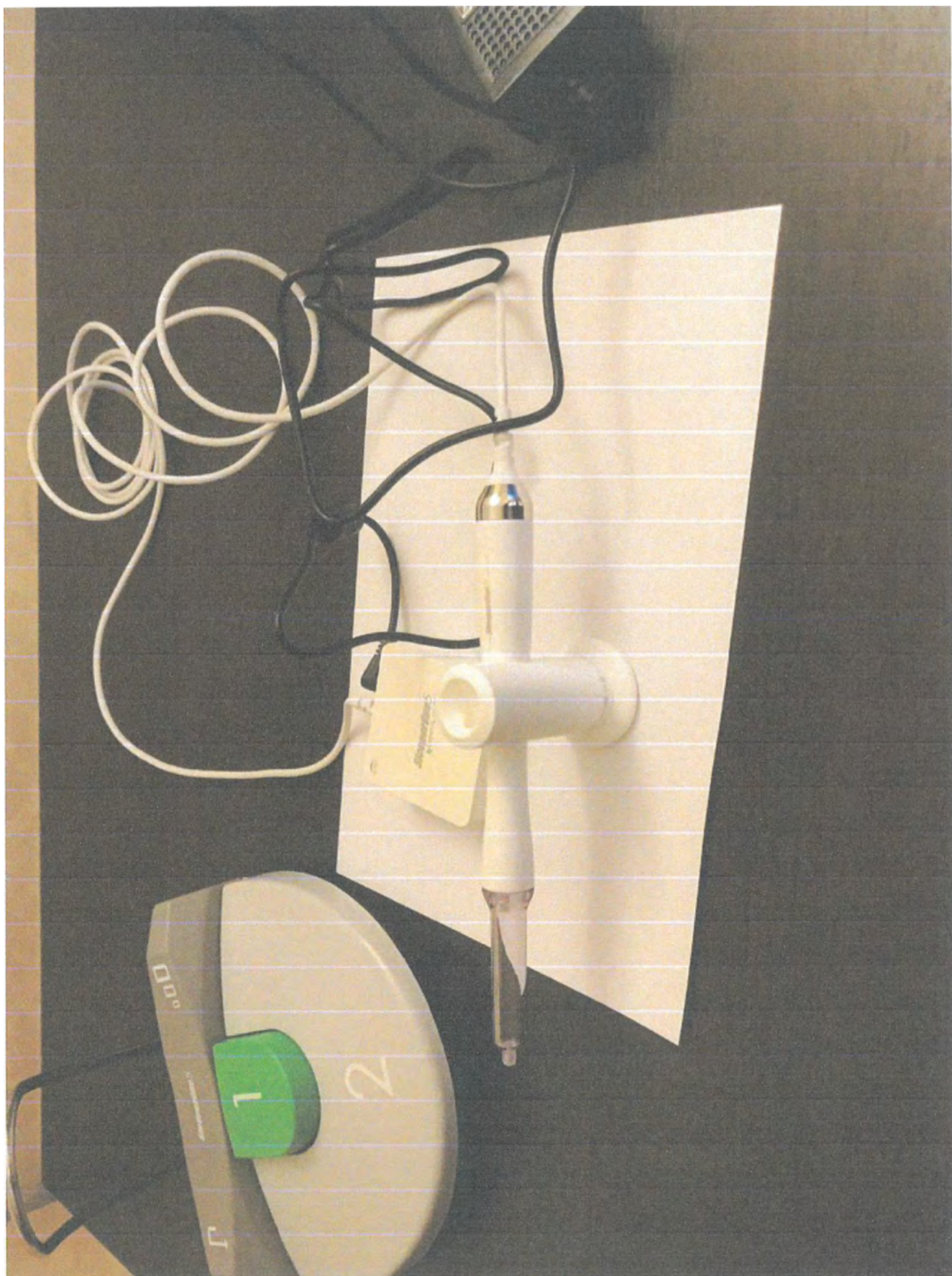
Système électronique d'anesthésie dentaire
Electronic system for dental anesthesia



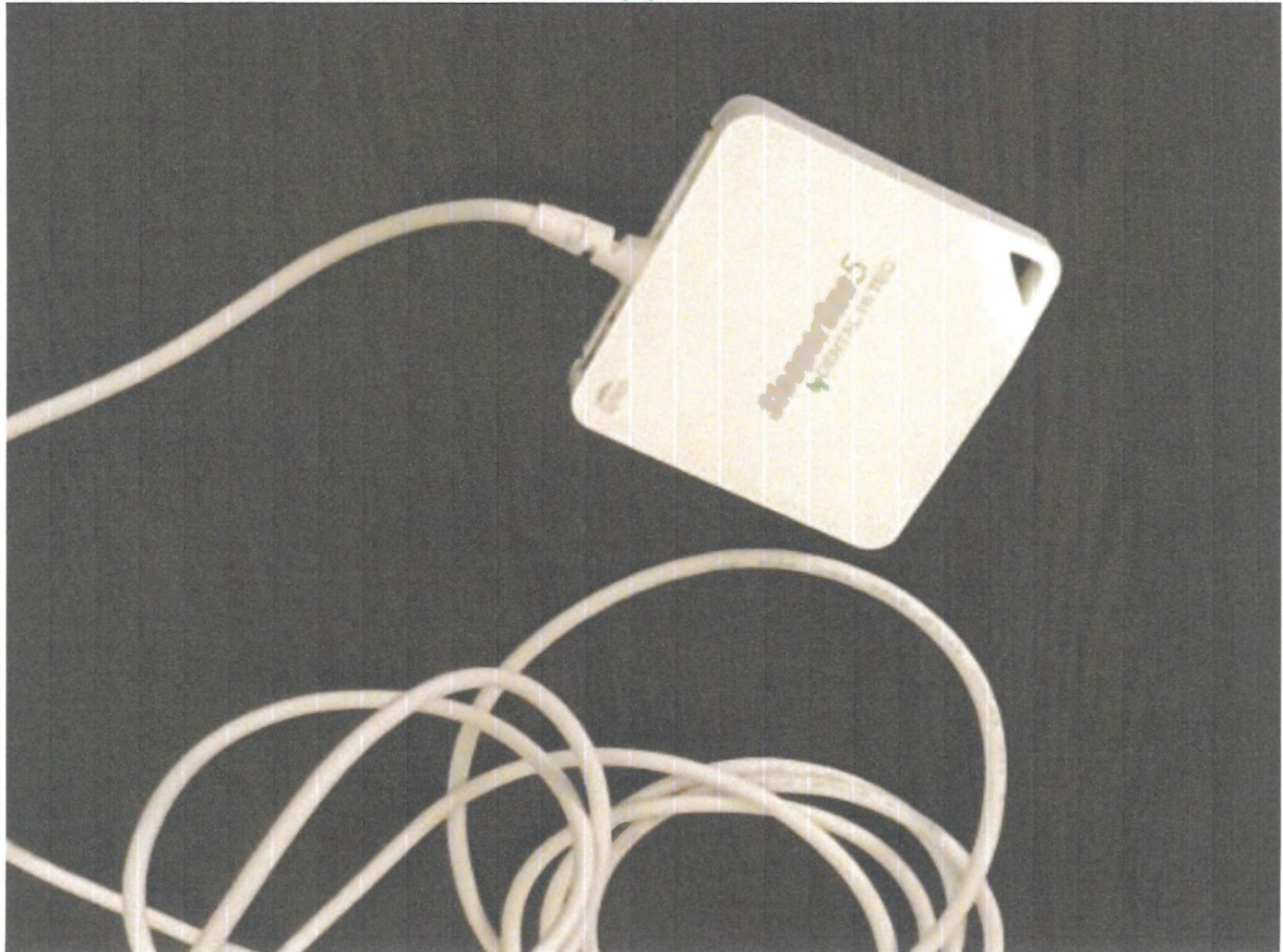
DENTAL HI TEC

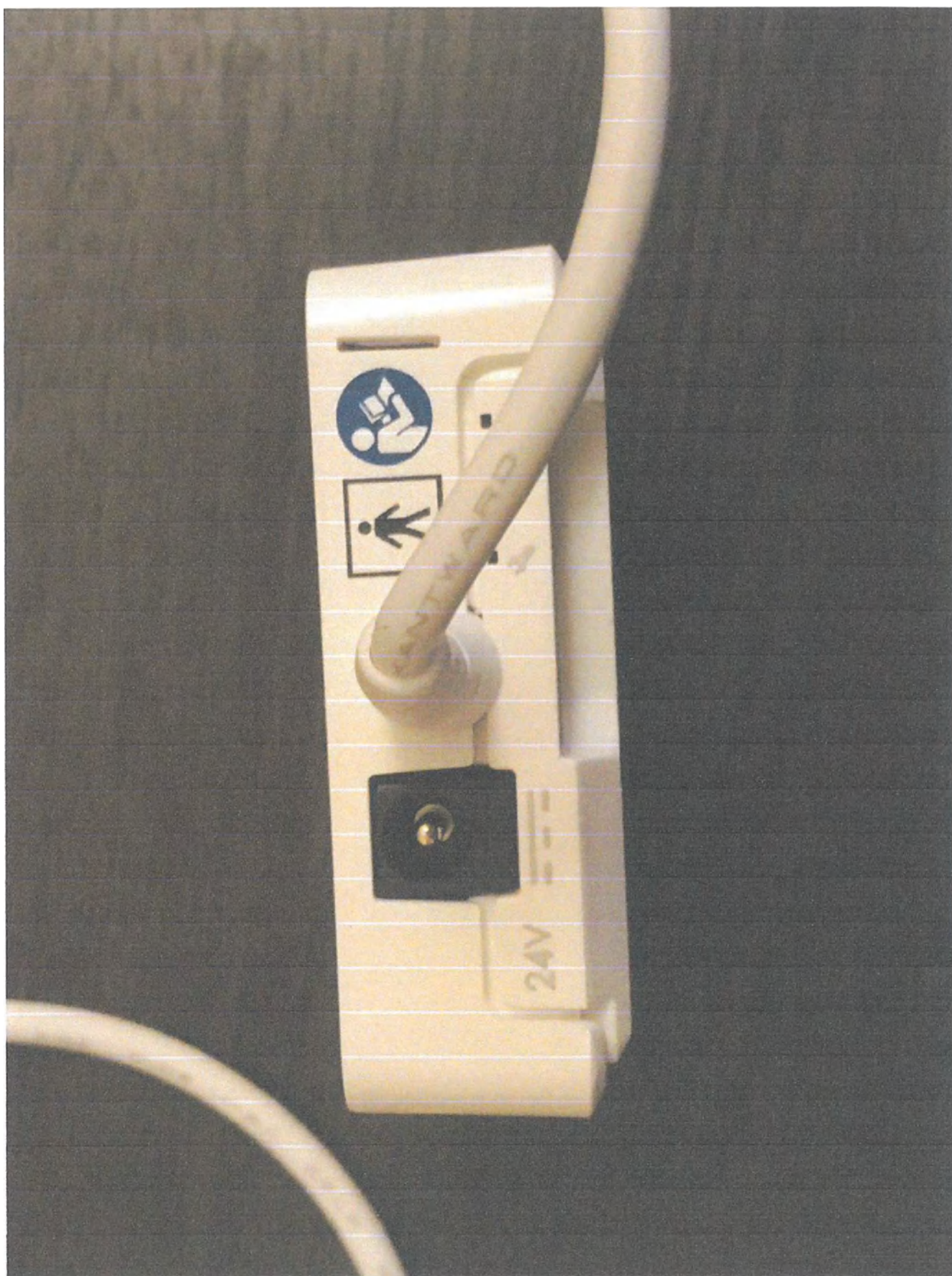
Leader in dental anesthesia





1. Блок управления



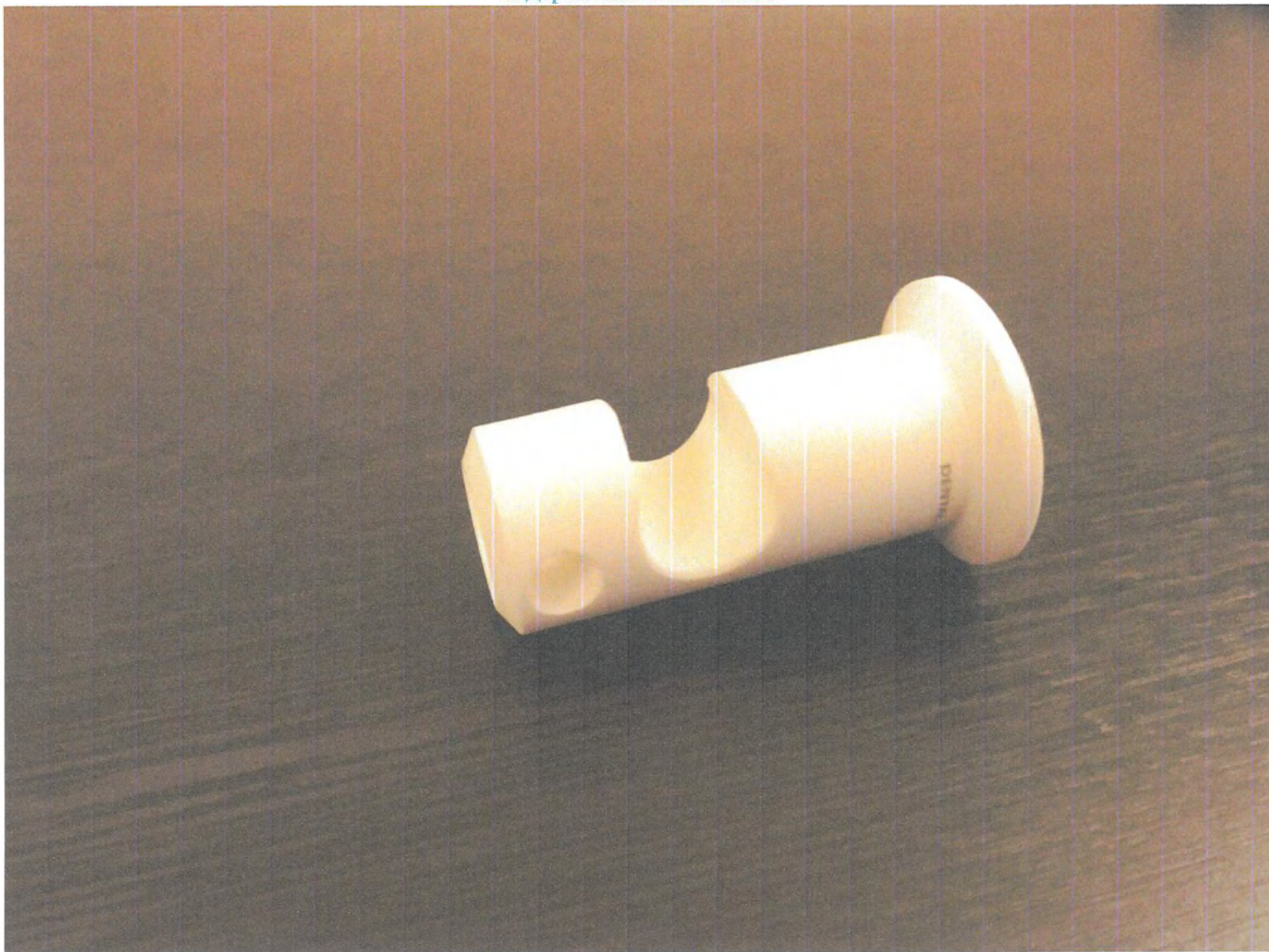








3. Держатель наконечника



3M
VHB™

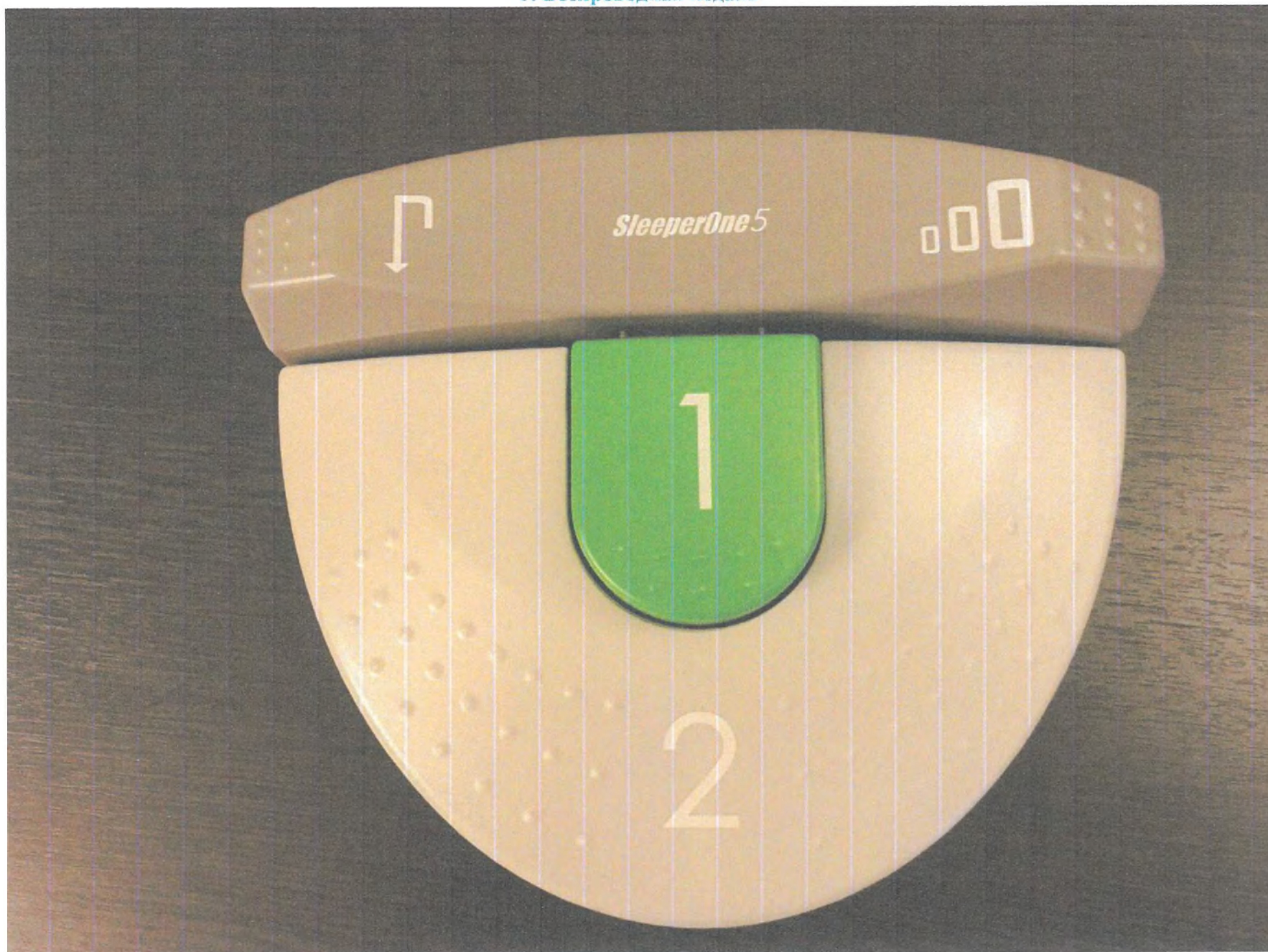
- Ⓒ **Surface Cleaner Sachet**
For use with 3M™ VHB™ Tapes
- Ⓕ **Pochette de Nettoyage**
A utiliser avec les rubans 3M™ VHB™
- Ⓓ **Reinigungstuch**
Für den Einsatz mit 3M™ VHB™ Klebeband
- Ⓖ **Oppervlaktereiniger**
Voor gebruik met 3M™ VHB™ Lijmstrips
- Ⓘ **Salvietta Detergente**
Da utilizzare con nastri acrilici 3M™ VHB™
- Ⓕ **Puhdistuspyyhe**
Käytettäväksi 3M™ VHB™ teippien kanssa
- Ⓔ **Ytrensörings servett**
För användning tillsammans med 3M™ VHB™ Tejper



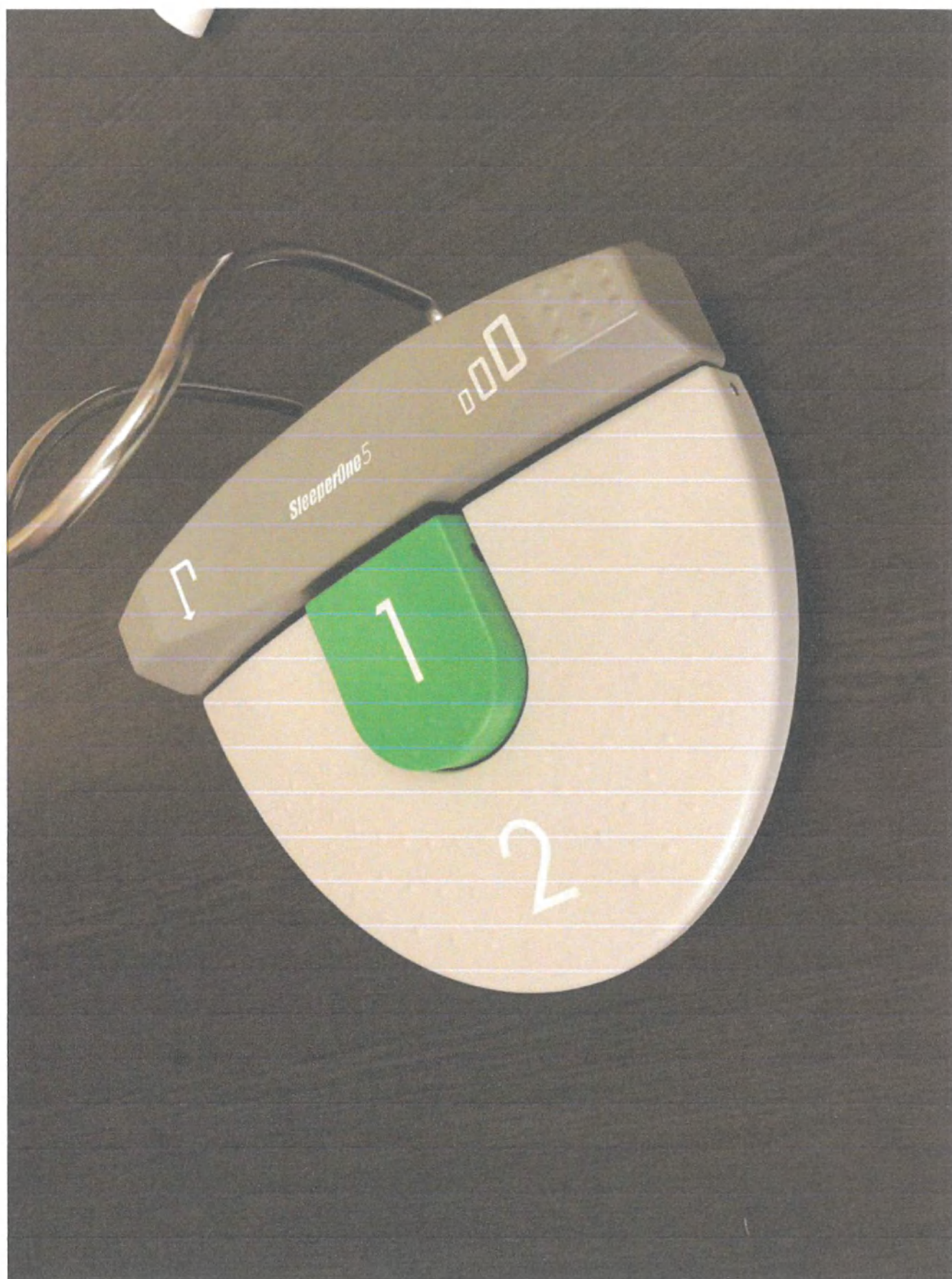
- © 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berks., RG12 8HT,
Tel: 01344 858 000. 3M Ireland Ltd., The Iveagh Building, The Park,
Carrickmines, Dublin 18 - Tel.: 01 2803555
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- © 3M Svenska AB, 191 89 Sollentuna - Tel.: 08-92 21 00

FY51001-7340-90511

5. Беспроводная педаль







6. Источник питания



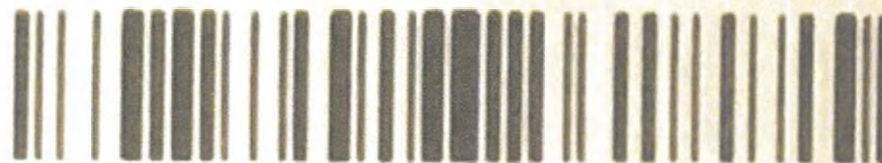
EAC

MEAN WELL ENTERPRISES CO.,LTD.
No. 28, Wuquan 3rd Rd., Wugu Dist.,
New Taipei City, 24891, Taiwan

Manual:
[www.
meanwell.
com/
manual.html](http://www.meanwell.com/manual.html)



This device complies with
Part 15 of the FCC Rules.
Operation is subject to the
following two conditions:
(1) this device may not cause
harmful interference, and
(2) this device must accept
any interference received,
including interference that
may cause undesired
operation.



OYB8306409





Order No.:
GSM36B24-P6L

AC / DC MEDICAL ADAPTOR

MODEL NO. : GSM36B24

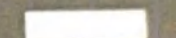
INPUT : 100-240VAC, 50/60Hz, 0.9-0.45A

OUTPUT : 24V $\equiv$ 1.5A, 36W MAX.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



MADE IN CHINA



C  US
E227340

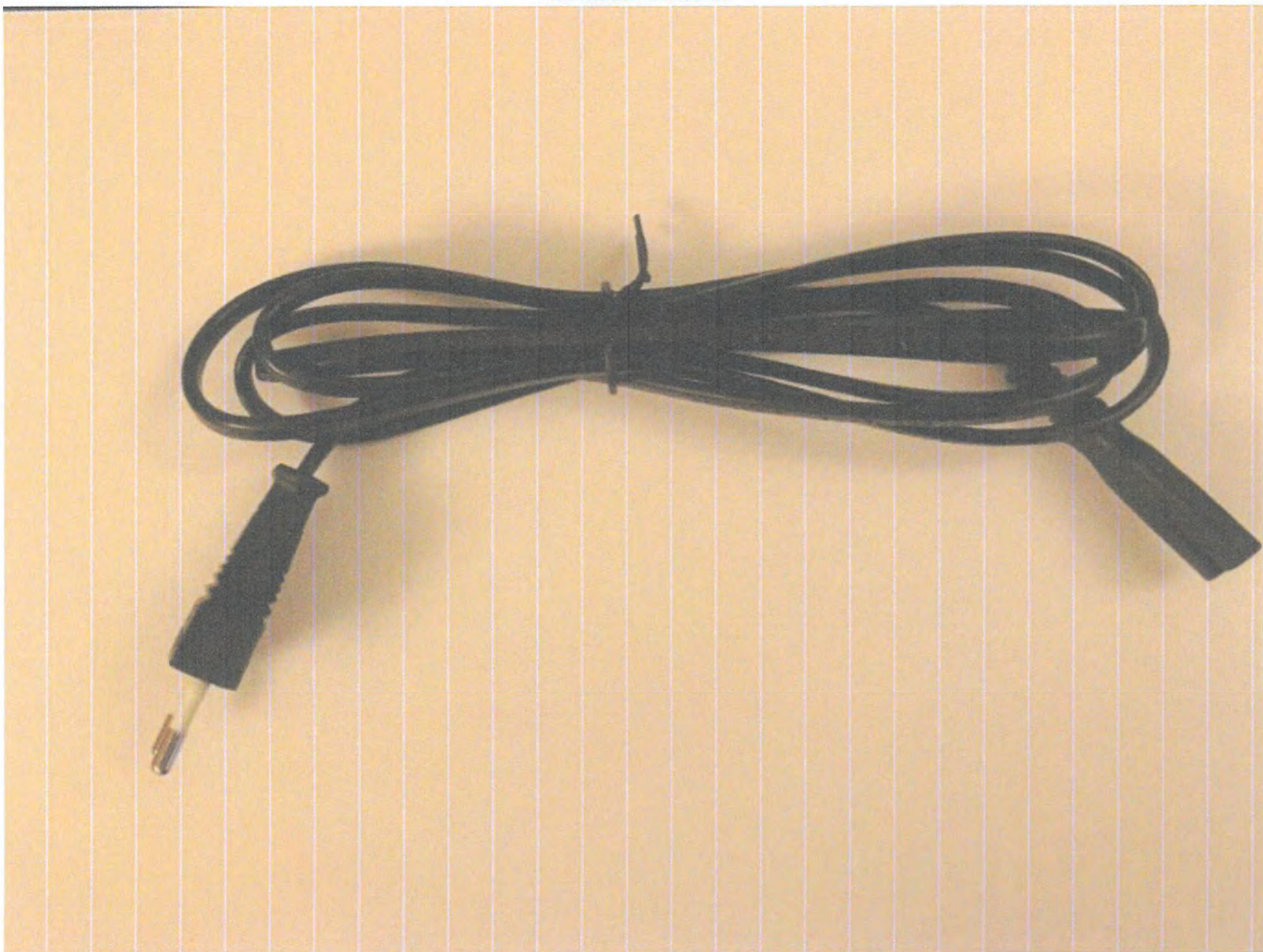
IP22



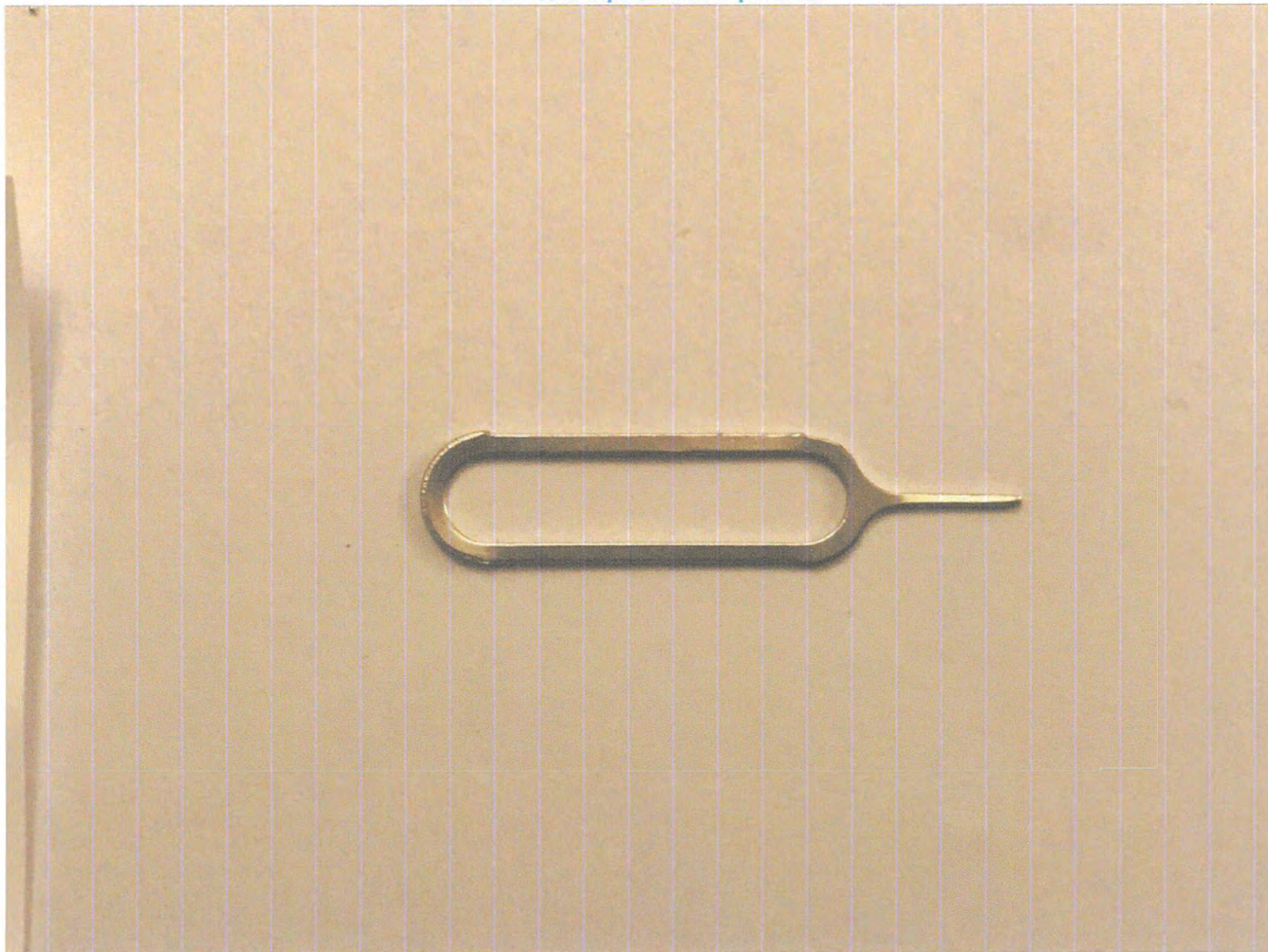
Indoor use only

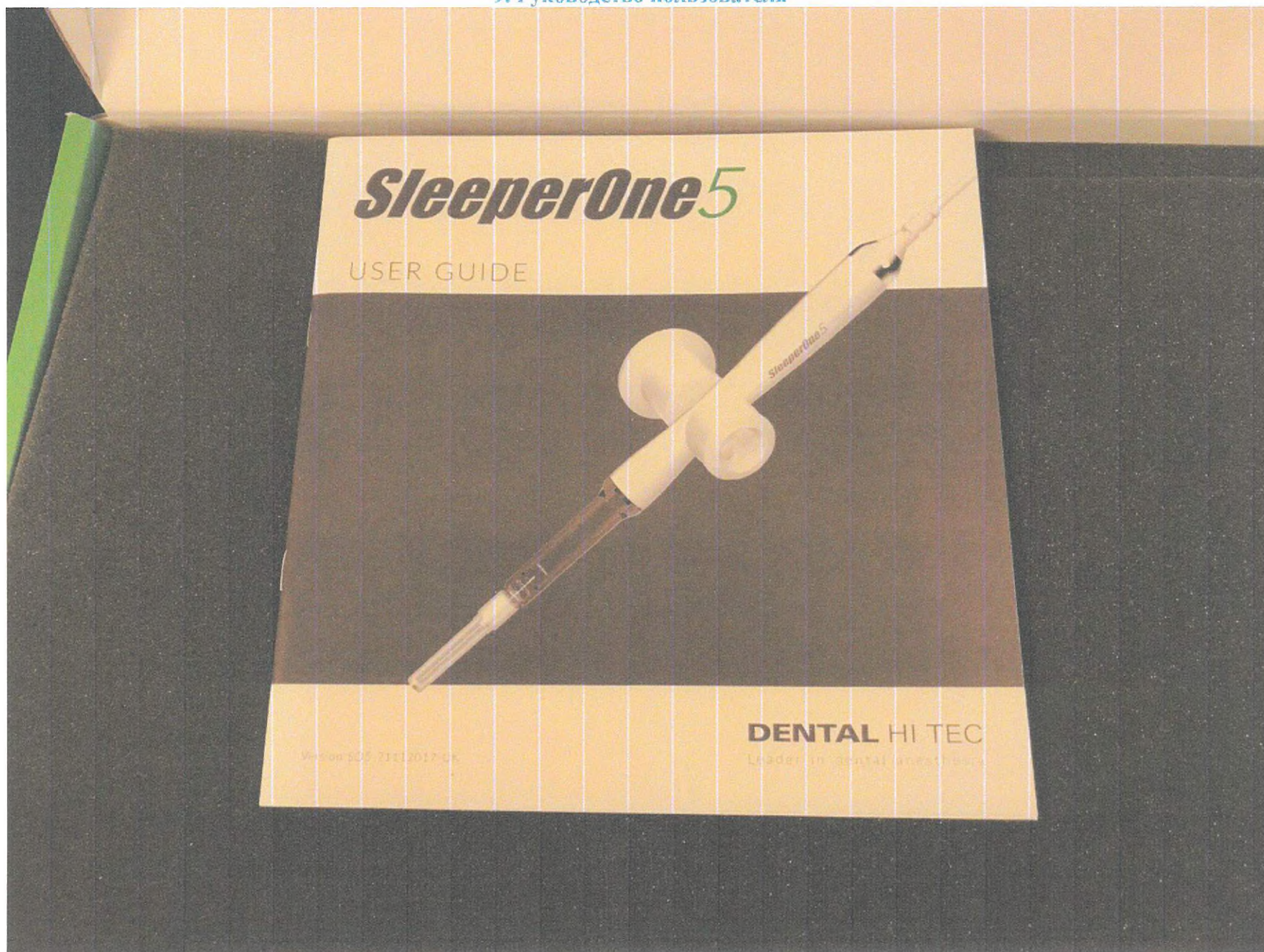
MW03

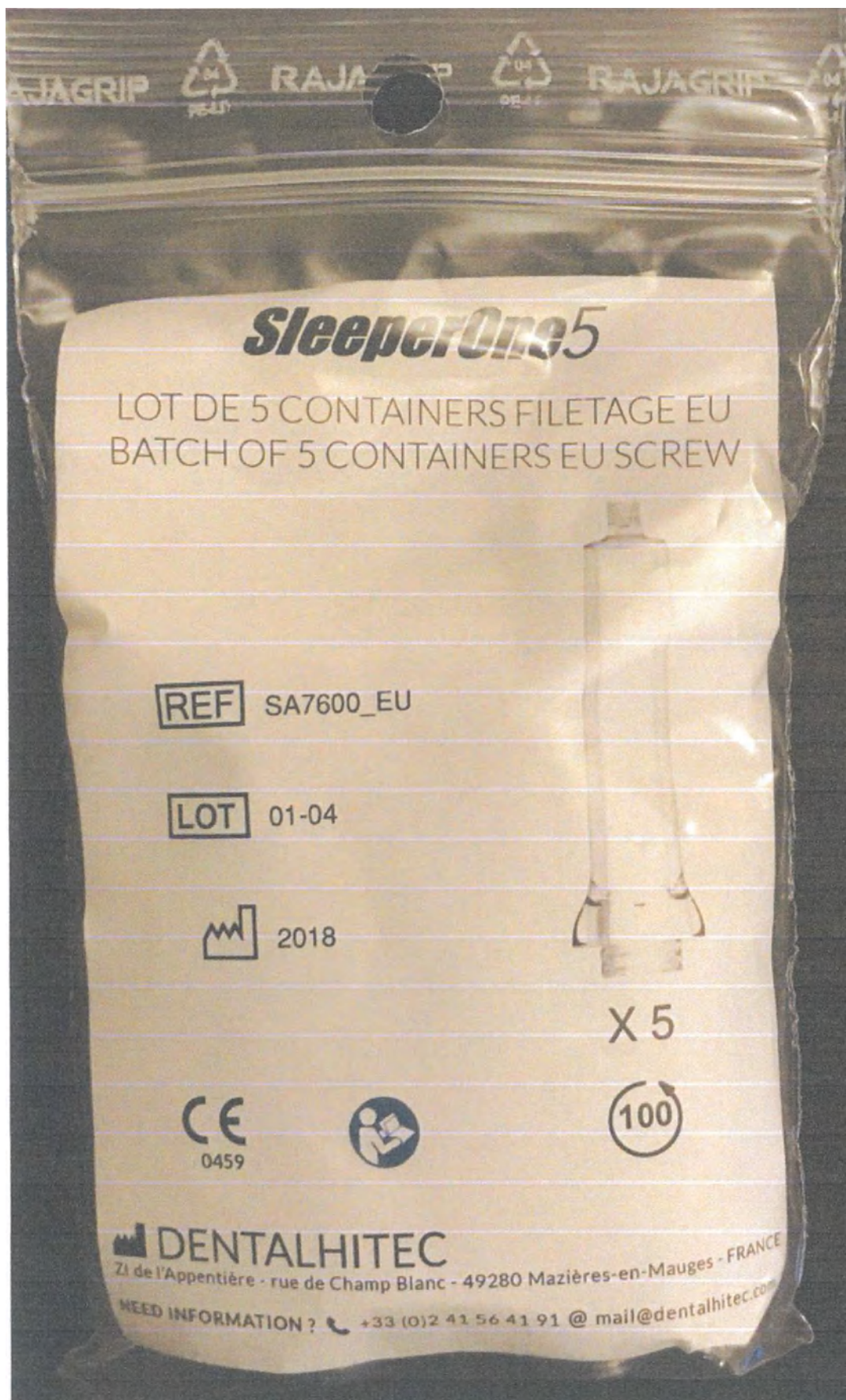
7. Кабель питания



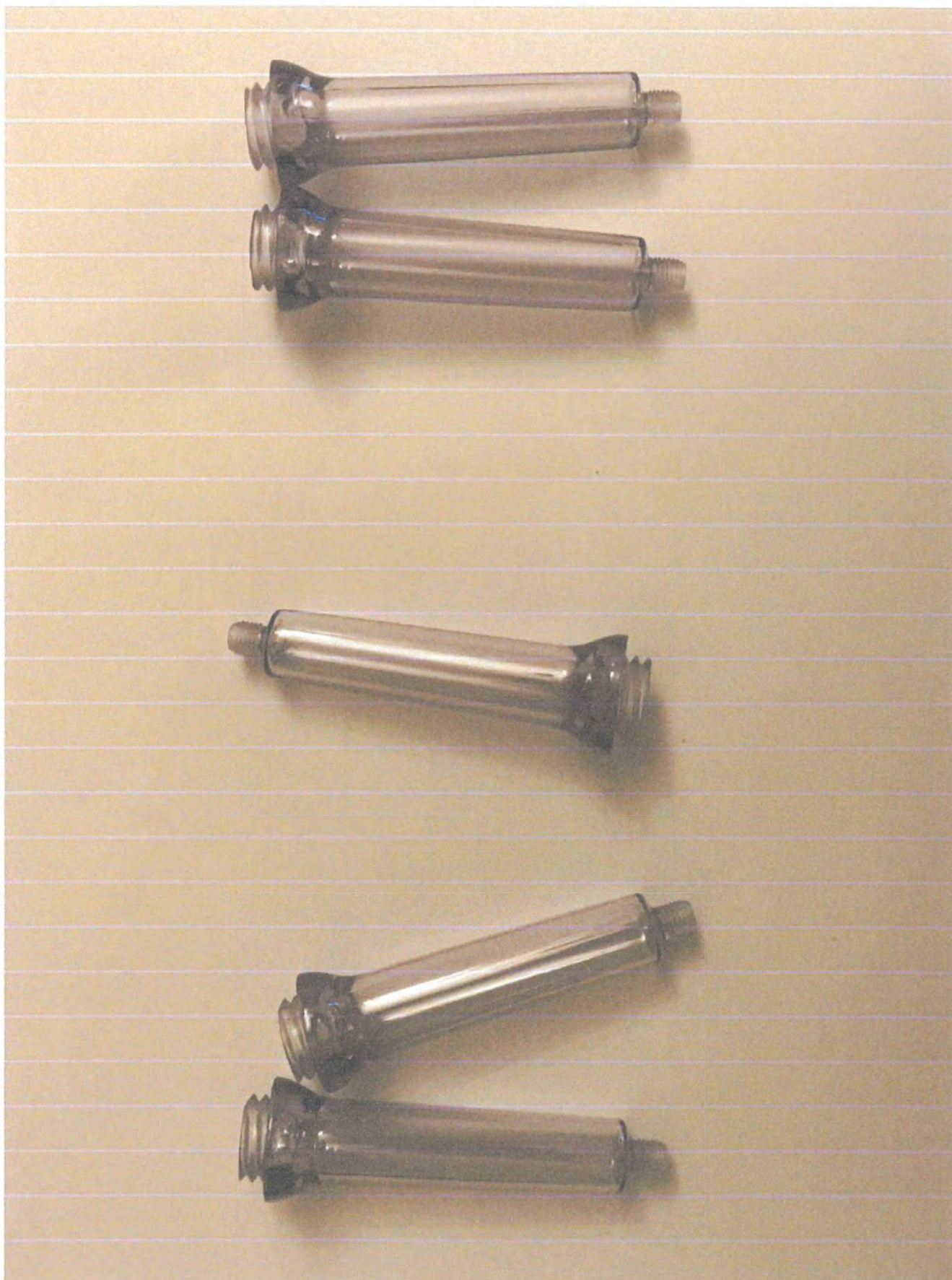
8. Ключ для переключения режимов







10. Насадка автортавирүемая пластиковая



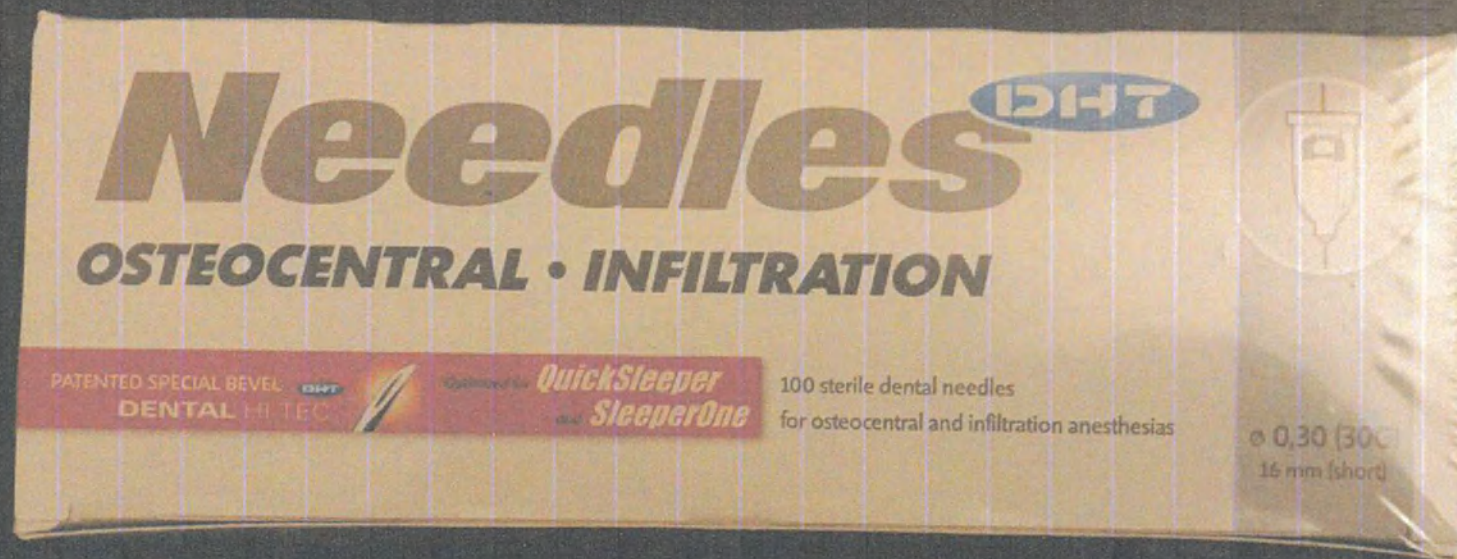


79



11. Иглы стоматологические стерильные одноразовые (Иглы DHT), стартовый набор:

- игла 30G – 16мм



Σ 2023-12
LOT F08172AA

##

STERILE R



SOFIC
3 rue Jean-Jacques Rousseau
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F 81207 MAZAMET CEDEX

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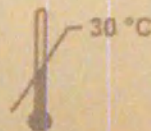
STERILE

For USA : Rx Only

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CE
0 0 8 6



Ne pas plier l'aiguille avant et après usage.

Do not fold the needle before and after use.

No doblar la aguja antes ni después del uso.

Réservé à l'usage professionnel en médecine bucco-dentaire.

For professional use only in the practice of dentistry.

Producto reservado exclusivamente para el uso del especialista en odontoestomatología.

LOT



Voir sous la boîte

See bottom side
of the box.

Ver en la parte
inferior de la caja.



ø 0,30 (30G) - 16 mm (short)

OSTEOCENTRAL • INFILTRATION



Anesthésie en muqueuse attachée
Anesthesia of the attached mucosa
Anestesia de la mucosa adherida

Aiguilles^{DHT}

Aiguilles à usage unique. Ne pas restériliser ou réutiliser.
À conserver dans son emballage d'origine jusqu'à utilisation.
Pour bénéficier de tous les avantages des aiguilles DHT, procédez comme indiqué ci-dessous.
Pour des performances maximales, l'utilisation d'une seringue avec prise stylo (points d'appui) et injection électronique est fortement conseillée.

Veillez à correctement orienter le repère de l'aiguille pour ce type d'anesthésie :

ANESTHÉSIE EN MUQUEUSE ATTACHÉE :

Pour une pénétration indolore même chez l'enfant, orientez le repère à l'opposé de la muqueuse et inclinez l'aiguille pour qu'elle soit presque parallèle à la muqueuse (1).
Enfoncez délicatement le biseau de moins d'un millimètre en injectant très lentement.

Needles^{DHT}

Single use needles. Do not resterilize or reuse.
Store in original packaging until ready to use.
In order to benefit from all of the advantages of the DHT needles, proceed as indicated below.
For maximum performance, the use of a syringe allowing the use of a pen grip (support points) and an electronic injection is highly recommended.

Be sure to correctly orientate the needle indicator for this type of anesthesia:

ANESTHESIA OF THE ATTACHED MUCOSA:

For a pain free penetration even with children, orientate the indicator opposite the mucosa and incline the needle so that it is almost parallel to the mucosa (1). While injecting very slowly, delicately penetrate the bevel by less than a millimeter.

Agujas^{DHT}

Agujas de un solo uso. No reutilizar, reprocesar o reesterilizar.
Consérvese en el empaque de origen hasta el uso.
Para gozar de todas las ventajas de las agujas DHT, proceda como se indica más abajo.
Para un rendimiento óptimo, la utilización de una jeringa de tipo estilográfico (puntos de apoyo) e inyección electrónica es fuertemente aconsejada.

Asegúrese de orientar correctamente la señal del bisel para este tipo de anestesia :

ANESTESIA DE LA MUCOSA ADHERIDA:

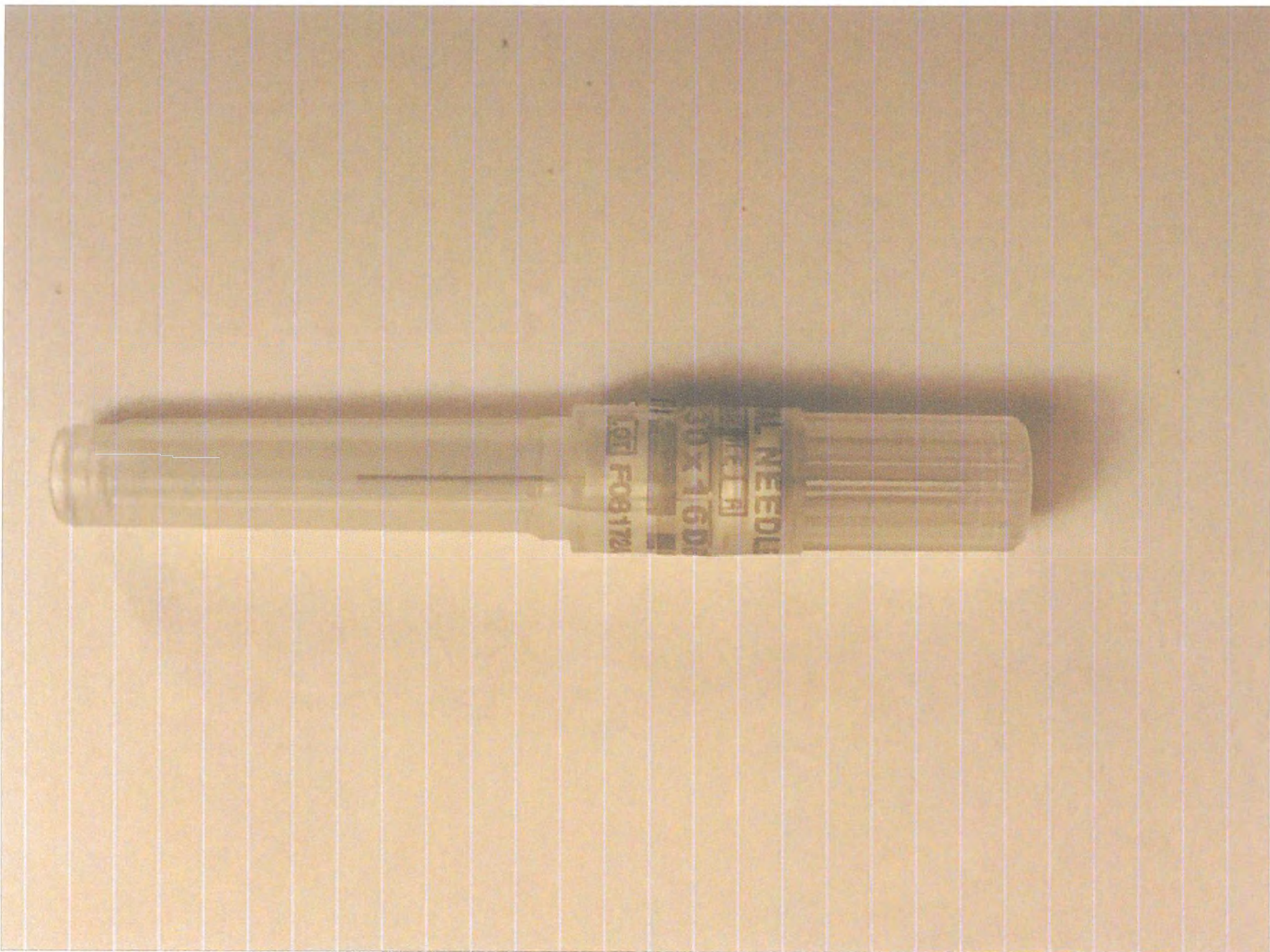
Para una penetración sin dolor incluso para los niños, oriente la señal del bisel enfrente a la mucosa y la inclinación de la aguja de manera casi paralela a la mucosa (1).
Inserte suavemente el bisel de menos de un milímetro debajo de los tejidos y inyecte el producto anestésico muy lentamente.

Plus d'information sur www.dentalhitec.com
(vidéos d'anesthésie avec les aiguilles DHT...)

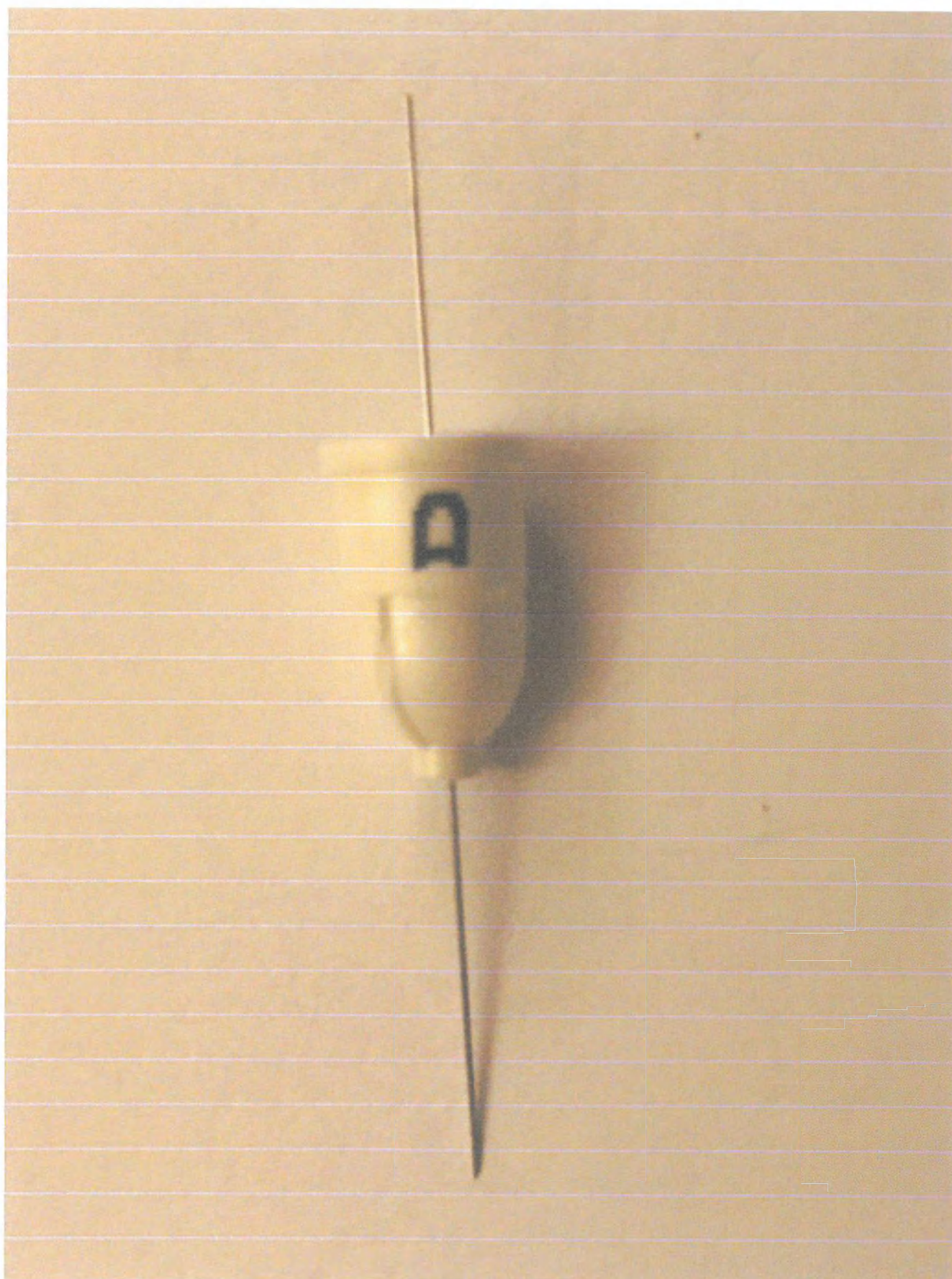
More information : www.dentalhitec.com
(videos with needles DHT...)

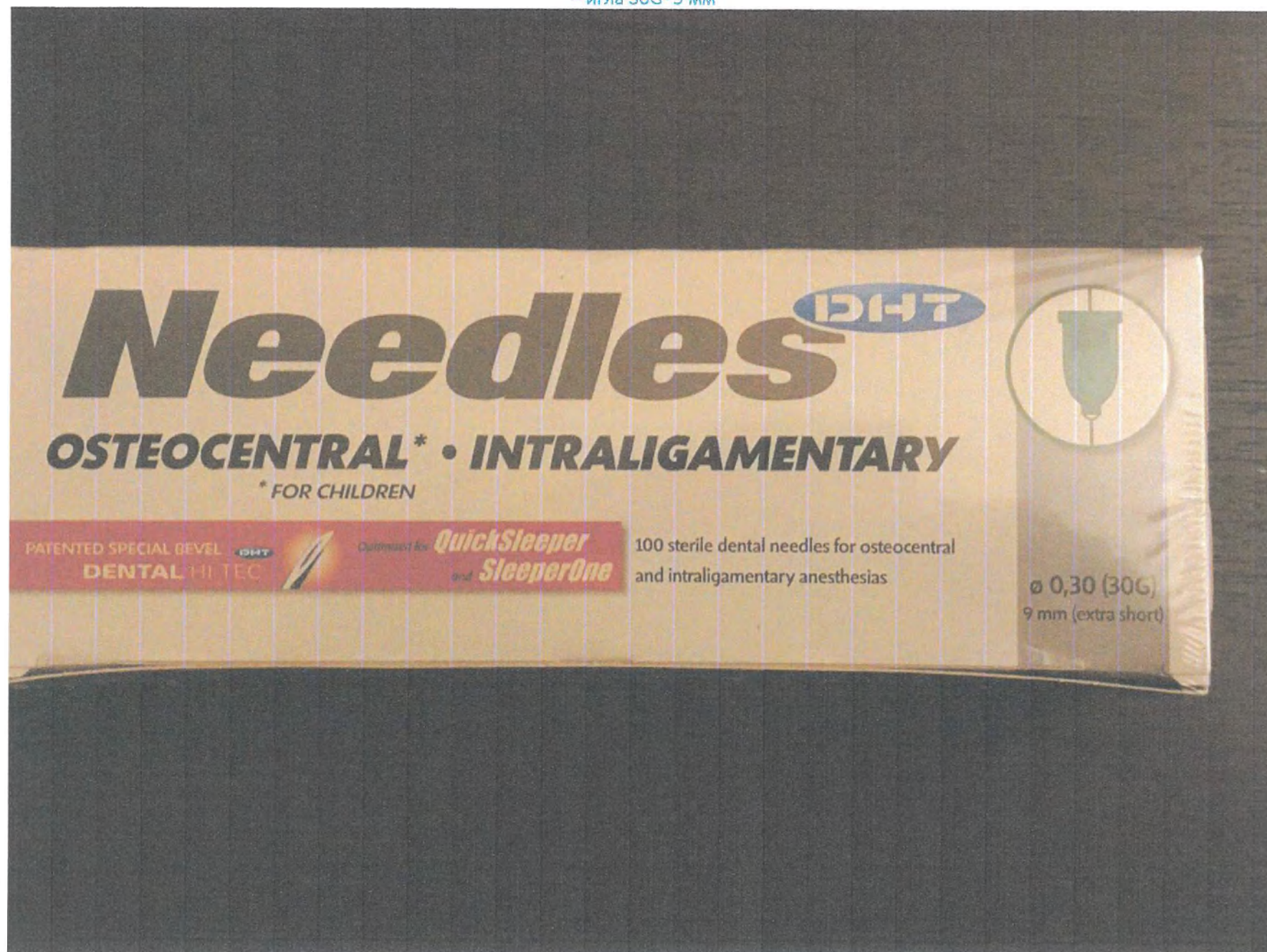
Más información : www.dentalhitec.com
(videos con agujas DHT...)

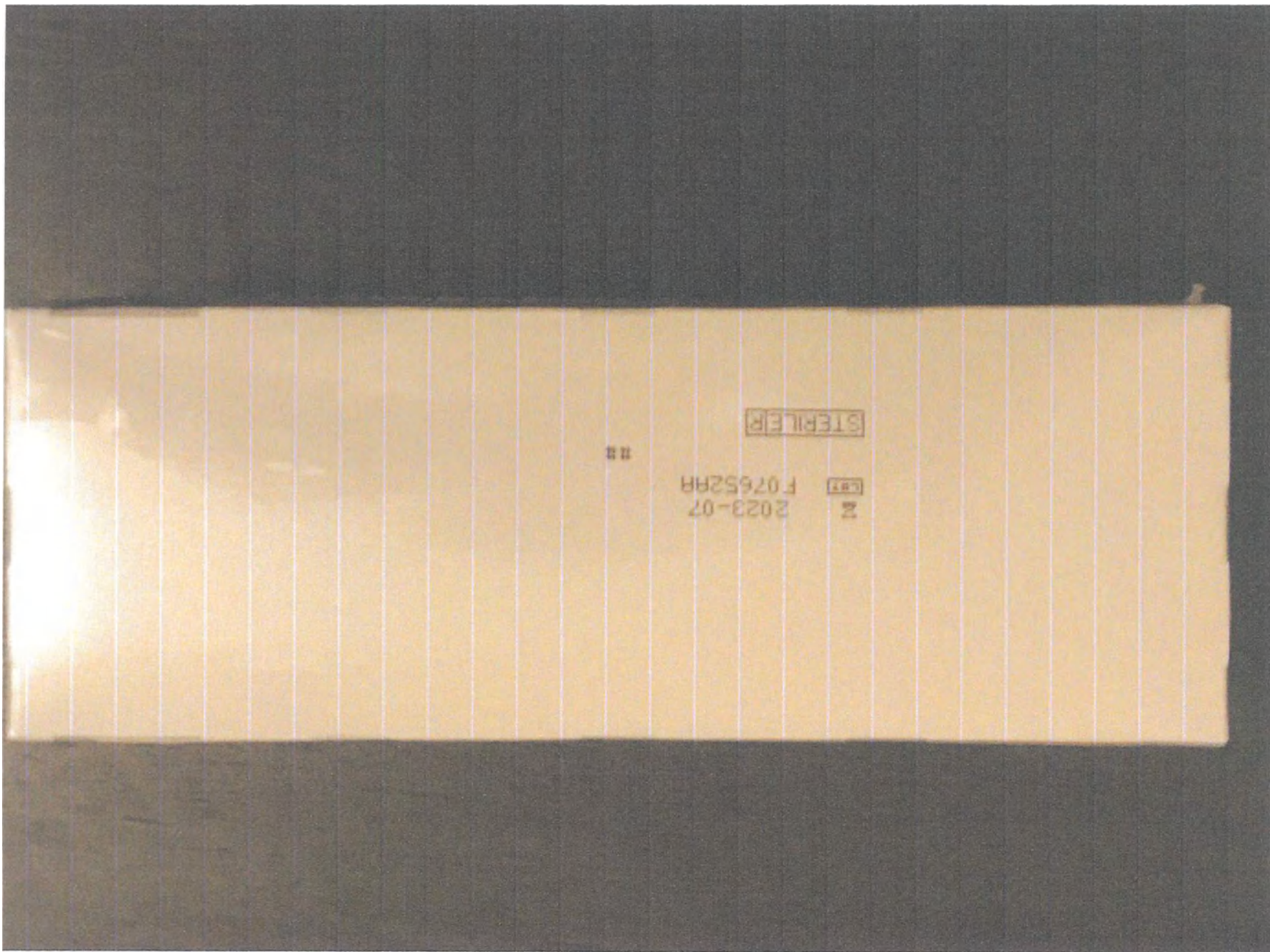












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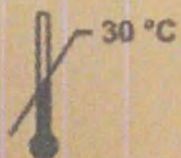
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Producto reservado exclusivamente para el uso del especialista en odontoestomatología.



Voir sous la boîte

See bottom side
of the box.

Ver en la parte
inferior de la caja



ø 0,30 (30G) - 9 mm (extra short)

OSTEOCENTRAL* • INTRALIGAMENTARY

*** FOR CHILDREN**

Agulhas

Needles

Agulhas à usage único. Não são esterilizadas no estéril.
A conservação deve ser realizada de acordo com as instruções.
Para utilização de uso único, não utilize a agulha DHT para
dois procedimentos. (1) Reutilização. Utilização de um mesmo
para dois procedimentos consecutivos. Utilização de um mesmo
para dois procedimentos consecutivos. Utilização de um mesmo
para dois procedimentos consecutivos.

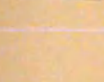
Vigilância sanitária: consultar o registro da agulha para o
tipo de anestésico.

ANESTÉSICO EM ANESTÉSICO ATACHADO

Para uso em anestésico atachado, a agulha deve ser
utilizada para a injeção de anestésico atachado, sem
que haja qualquer contato com a mucosa. (2) Não utilizar a
agulha para a injeção de anestésico atachado em
anestésico atachado.

ANESTÉSICO INTRALIGAMENTAR

Para uso em anestésico intraligamentar, a agulha deve ser
utilizada para a injeção de anestésico intraligamentar, sem
que haja qualquer contato com a mucosa. (2) Não utilizar a
agulha para a injeção de anestésico intraligamentar em
anestésico intraligamentar.



1
Insere a agulha no interior da seringa.



2
Insere a agulha no interior da seringa, sem que haja qualquer contato com a mucosa.

Needles

Needles

Single use needles. Do not reuse or reuse.
Store in original packaging and ready to use.
To use, insert the needle into the syringe barrel.
(1) Reutilization. Utilization of a single needle for
two consecutive procedures. Utilization of a single needle for
two consecutive procedures. Utilization of a single needle for
two consecutive procedures.

Be sure to correctly orientate the needle indicator for this type
of anesthesia.

ANESTHESIA OF THE ATTACHED MUCOSA

For a single use attached mucosa anesthesia, use the
needle to inject the attached mucosa, without any contact
with the mucosa. (2) Do not use the needle for
injection of attached mucosa anesthesia in attached
mucosa anesthesia.

INTRALIGAMENTARY ANESTHESIA

For a single use intraligamentary anesthesia, use the
needle to inject the intraligamentary anesthesia, without
any contact with the mucosa. (2) Do not use the needle
for injection of intraligamentary anesthesia in
intraligamentary anesthesia.

Agulhas

Agulhas

Agulhas de uso único. Não reutilizar nem
reutilizar. Armazenar no original e pronto para uso.
Para utilizar, insira a agulha no interior da seringa.
(1) Reutilização. Utilização de uma mesma agulha para
dois procedimentos consecutivos. Utilização de uma mesma
agulha para dois procedimentos consecutivos. Utilização de uma
agulha para dois procedimentos consecutivos.

Antes de utilizar, certifique-se de que a agulha esteja
orientada corretamente para o tipo de anestésico.

ANESTÉSICO DA MUCOSA ADJACENTE

Para anestésico da mucosa adjacente, utilize a agulha para
a injeção de anestésico da mucosa adjacente, sem que
haja qualquer contato com a mucosa. (2) Não utilize a
agulha para a injeção de anestésico da mucosa adjacente
em anestésico da mucosa adjacente.

ANESTÉSICO INTRA LIGAMENTAR

Para anestésico intra ligamentar, utilize a agulha para
a injeção de anestésico intra ligamentar, sem que
haja qualquer contato com a mucosa. (2) Não utilize a
agulha para a injeção de anestésico intra ligamentar
em anestésico intra ligamentar.

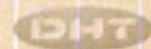
More information: www.dentalhite.com
(vidéos avec agulhas DHT...)

More information: www.dentalhite.com
(vidéos with needles DHT...)

Plus d'information sur www.dentalhite.com
(vidéos d'anesthésie avec les agulles DHT...)



Agulhas
OSTEOCENTRAL - INTRALIGAMENTAR



DENTAL HI TEC

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www.dentalhitec.com

Aiguilles^{DHT}
Needles^{DHT}
Agujas^{DHT}



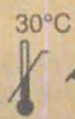
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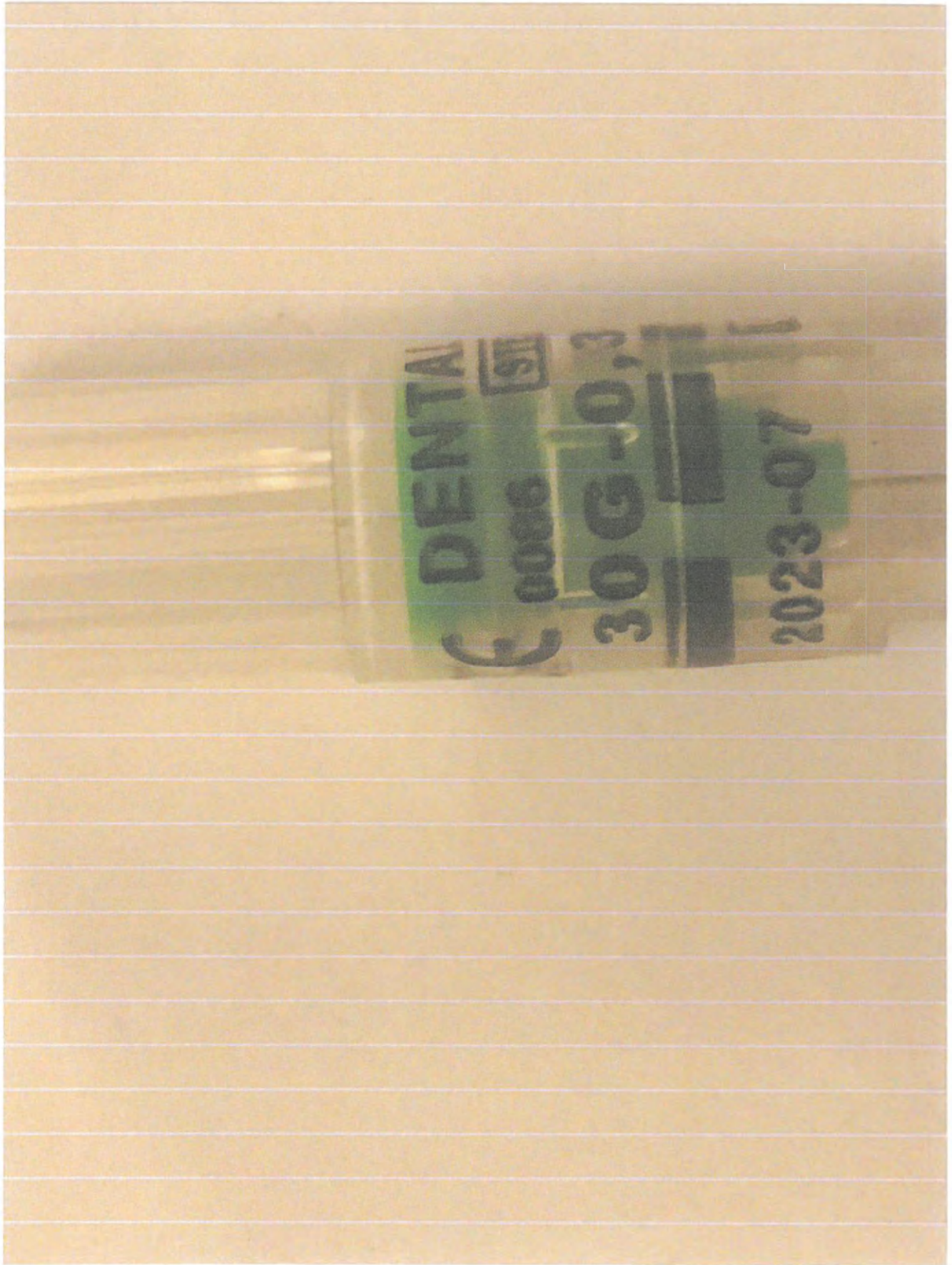


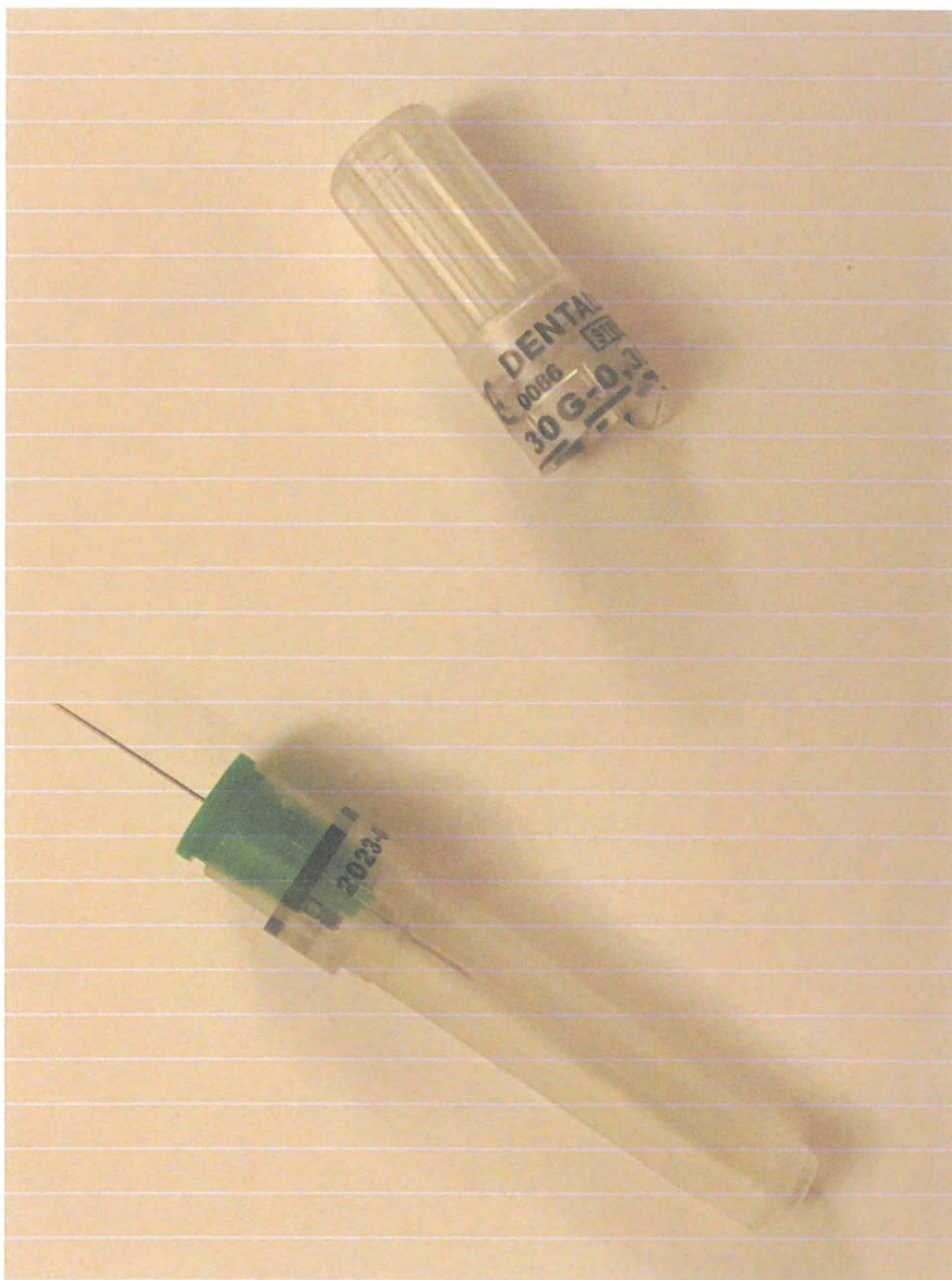
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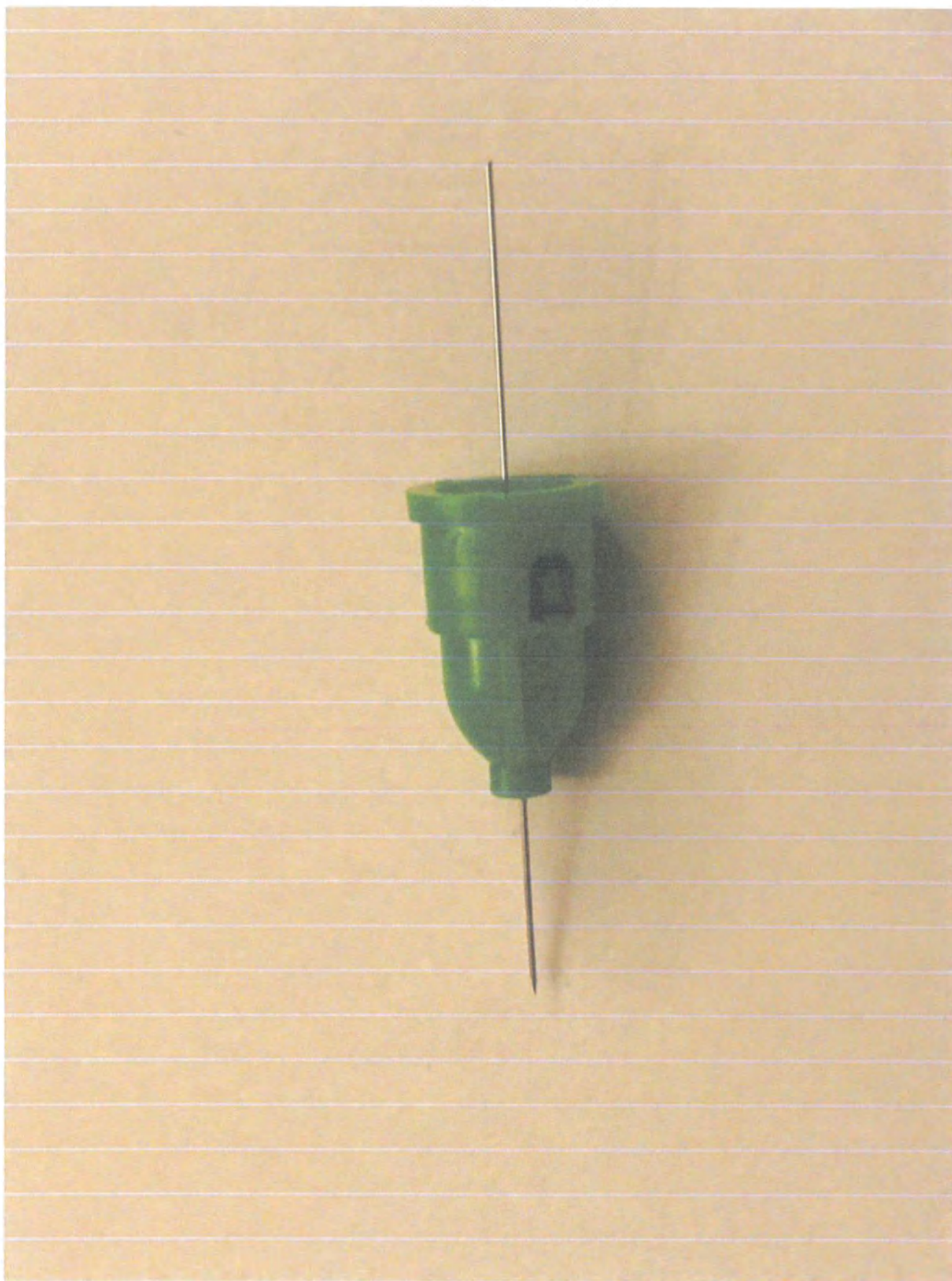


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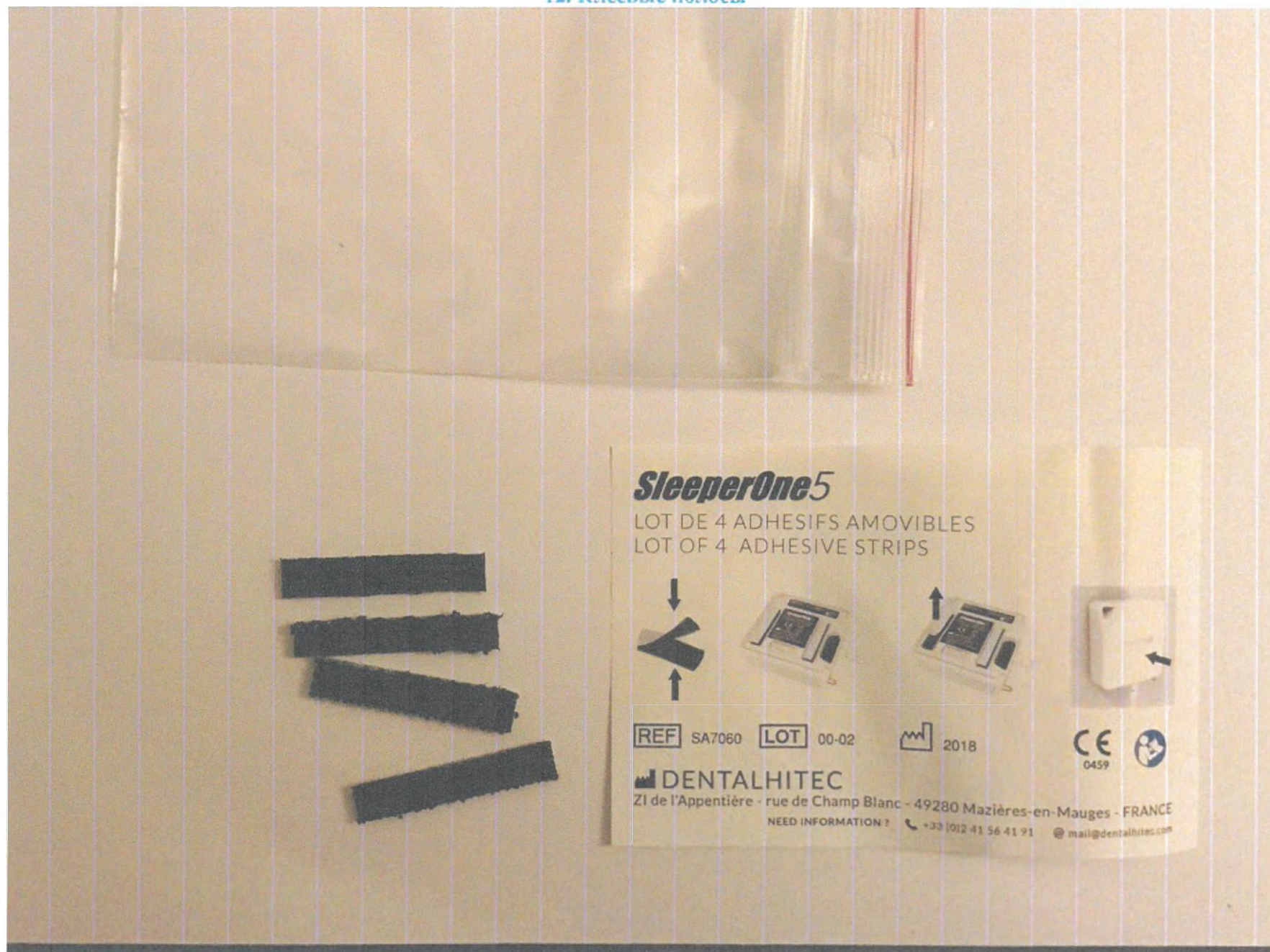
PRODHT/10/12-V4 IP







12. Клеевые полосы







Всего прошнуровано,
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печатью 100 лист (ов)



М.В. Званская

«УТВЕРЖДАЮ»

Генеральный директор
ООО «ТС Дентал»

М.В. Званская



Макет маркировки медицинского изделия на русском языке

«Дозатор стоматологический шприцевой автоматический, варианты
исполнения QuickSleeper и SleeperOne5»,
производства DENTAL HI TEC (ДЕНТАЛ ХИ ТЕК), Франция



**Дозатор стоматологический шприцевой автоматический,
вариант исполнения QuickSleeper**

РУ № РЗН 20XX/XXXX от XX.XX.20XX

Информация о технике безопасности и
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инструкции по эксплуатации.



Информация об условиях транспортировки и хранения
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ТЕК)
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mail@dentalhitec.com

**Уполномоченный
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ООО «ТС Дентал»
123242, Россия, г. Москва,
Столярный пер, д.2
тел.: 8 (495) 921 35 06
info@tsdental.ru



**Дозатор стоматологический шприцевой автоматический,
вариант исполнения SleeperOne5**

РУ № РЗН 20XX/XXXX от XX.XX.20XX

Информация о технике безопасности и
использовании по назначению представлена в
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М.В. Званская