

## SCHEDA TECNICA – HELIX TEST



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### 1. Dati preliminari

<b>Nome prodotto</b>	<b>Helix test</b>
<b>Codice prodotto</b>	OXC40002
<b>Descrizione breve</b>	Kit Helix Test per il controllo dei carichi cavi in sterilizzatrici a vapore con pre-vuoto.
<b>Imballo primario</b>	Busta
<b>Imballo secondario</b>	Cartone
<b>Unità minima di vendita</b>	200 pezzi / 1 supporto per busta, 20.000 pezzi per cartone (100 buste da 200 pz)

#### Mediline S.r.l.

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## 2. Dati normativi

<b>Tipo prodotto</b>	<b>Test sterilizzazione</b>
<b>Fabbricante</b>	Mediline Srl, via Balme 33/C, 10143 Torino (Italia)
<b>Conformità a Regolamenti e Norme internazionali</b>	EN 867-5, ISO 11140-1:2005 classe 2

## 3. Descrizione e uso previsto

Kit Helix Test per il controllo dei carichi cavi in sterilizzatrici a vapore con pre-vuoto. Dispositivo riutilizzabile per validazione e rilascio carico e controllo giornaliero.

## 4. Caratteristiche principali

Caratteristica	Valore
<b>Parametri di processo</b>	3,5 min a 134°C; 15 min a 121°C; processo VAPORE
<b>Vita utile (mesi)</b>	36
<b>Conservazione dopo l'uso</b>	Una volta elaborate, le strisce di monitoraggio sono stabili e non richiedono particolari condizioni di conservazione.
<b>Origine prodotto</b>	Prodotto fabbricato in Paesi extra UE
<b>Smaltimento</b>	Busta: raccolta plastica; cartone: raccolta carta; seguire disposizioni locali
<b>Certificazioni</b>	Indicatori chimici tipo 4, test report ISO 11140-1:2005 (vedi allegati)
<b>Note</b>	Non contiene piombo/metalli pesanti; non adatto per validazione globale sterilizzazione

## 5. Istruzioni per l'uso

1. Svitare la capsula indicatrice dal cappuccio terminale della cannula.
2. Estrarre un indicatore del test Helix dalla busta protettiva e piegarlo a metà lungo la linea di incisione, con l'inchiostro dell'indicatore rivolto verso l'interno.
3. Inserirlo nella capsula indicatrice dalla parte piegata.
4. Riposizionare la capsula indicatrice avvitantola manualmente fino a quando non è ben stretta.
5. Posizionare il dispositivo Helix Test assemblato nello sterilizzatore, in posizione orizzontale, vicino al punto più

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freddo dello sterilizzatore.

6. Eseguire il ciclo di sterilizzazione previsto.

7. Al termine del ciclo, rimuovere il dispositivo Helix Test dallo sterilizzatore e attendere un minuto per farlo raffreddare prima di aprirlo.

8. Aprire la capsula indicatrice e rimuovere la striscia di monitoraggio dell'Helix Test. Leggere i risultati.

9. Documentare i risultati come richiesto dalle procedure ospedaliere.

## 6. Avvertenze e precauzioni

- Nel ciclo a 135°C non superare i 4 min. di tempo.

- Il test va eseguito con il cestello vuoto, prima del primo ciclo di sterilizzazione di ogni giornata.

- Questo prodotto non è adatto a valutare l'efficacia globale del processo di sterilizzazione a vapore per cui esistono specifici indicatori chimici o biologici.

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## 7. Immagine etichetta



**200**  
pezzi  
+ 1 supporto

# Helix Test

CONFORME ALLE NORME  
EN 867-5 E ISO 11140-1:2005  
CLASSE 2

Per controllo carichi cavi in  
sterilizzatrici a vapore con  
pre-vuoto tramite ciclo  
134 °C - 3,5 min. / 121 °C - 15 min.

**Esempio di cambio colore delle strisce  
indicatrici di vapore standard**

Temperatura, tempo e penetrazione del vapore  
sufficienti

Rimozione dell'aria e penetrazione del vapore  
insufficienti

Temperatura raggiunta, ma nessuna rimozione  
dell'aria e nessuna penetrazione del vapore

Temperatura insufficiente e nessuna rimozione  
dell'aria e nessuna penetrazione del vapore

01/07/2028

**LOT** MED20250702

02/07/2025

**Avvertenza!** Dopo l'uso il pacco  
potrebbe essere ancora caldo!

**STEAM**

+10°C +40°C

**REF** OXC40002

**Mediline S.r.l.**  
via Balme 33/C  
10143 Torino - Italia

Prodotto  
fabbricato in  
Paesi extra Ue

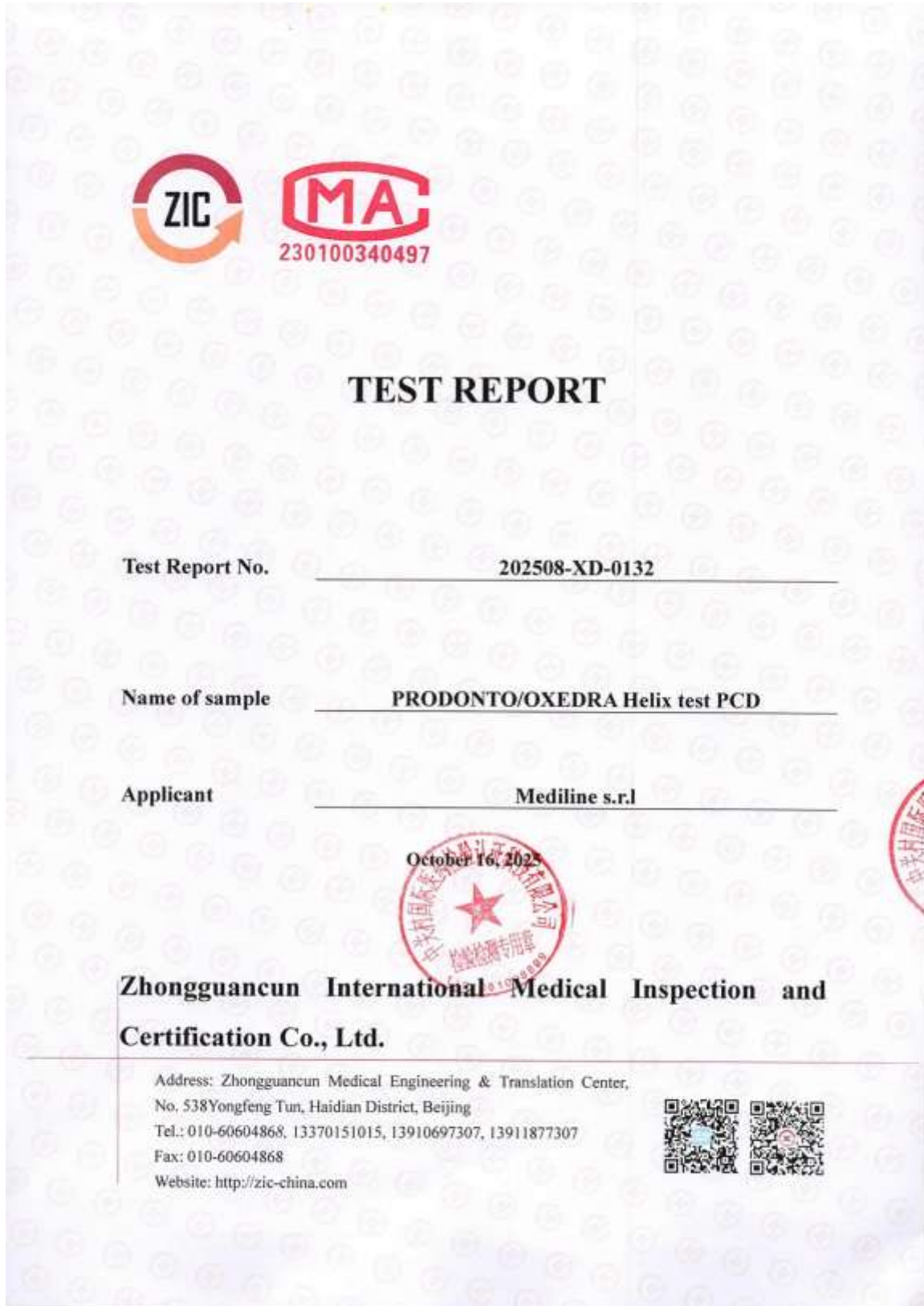
**oxedra**  
MEDICAL

Rev. 01.3025.06

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## 8. Test report EN 867-5



**ZIC** **MA**  
230100340497

### TEST REPORT

Test Report No. 202508-XD-0132


Name of sample PRODONTO/OXEDRA Helix test PCD

Applicant Mediline s.r.l

October 16, 2025

**Zhongguancun International Medical Inspection and Certification Co., Ltd.**

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No. 538 Yongfeng Tun, Haidian District, Beijing  
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Zhongguancun International Pharmaceutical  
Inspection and Certification Technology Co., Ltd.

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Name of Sample	<u>PRODONTO/OXEDRA Helix test</u> <u>PCD</u>	Samples Quantity	<u>2 sets (400</u> <u>PCS)</u>
Applicant company	<u>Mediline s.r.l</u>	Characteristic	<u>Solid</u>
Manufacturer	<u>[REDACTED]</u>	Received Date	<u>2025.08.08</u>
Lot No. of Sample	<u>Production date: July 02 2025</u> <u>production batch number: MED20250702</u>	Completion Date	<u>2025.09.17</u>
Specification	<u>/</u>		

**Test Standard and Method:**

According to the clause EN 867-5:2001 《Non-biological systems for use in sterilizers —Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S》 to test.

**Evaluation basis:**

The evaluation was conducted in accordance with the the requirements of EN 867-5:2001 《Non-biological systems for use in sterilizers —Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S》.

**Test Conclusions:**

1. The chemical indicator cards supporting the PRODONTO/OXEDRA Helix test PCD were tested under different conditions, with the following results: Under the condition of 121°C saturated steam for 15.0 minutes: The indicator on the tested chemical indicator cards reached the reference color; all biological indicators showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under the condition of 121°C saturated steam for 10.0 minutes: The indicator on the tested chemical indicator cards did not reach the reference color; among the biological indicators after cultivation, 2 showed negative results (no growth of *Bacillus stearothermophilus*) and 1 showed positive results (with growth of *Bacillus stearothermophilus*). Under the condition of 128°C saturated steam for 7.0 minutes: The indicator on the tested chemical indicator cards reached the reference color; all biological indicators showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under the condition of 128°C saturated steam for 2.0 minutes: The

(Carried forward)

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indicator on the tested chemical indicator cards did not reach the reference color; among the biological indicators after cultivation, 1 showed negative results (no growth of *Bacillus stearothermophilus*) and 2 showed positive results (with growth of *Bacillus stearothermophilus*). Under the condition of 134°C saturated steam for 3.5 minutes: The indicator on the tested chemical indicator cards reached the reference color; all biological indicators showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under the condition of 134°C saturated steam for 36 seconds: The indicator on the tested chemical indicator cards did not reach the reference color; all biological indicators showed positive results after cultivation, with growth of *Bacillus stearothermophilus*. Under the condition of 135°C saturated steam for 3.0 minutes: The indicator on the tested chemical indicator cards reached the reference color; all biological indicators showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under the condition of 135°C saturated steam for 29 seconds: The indicator on the tested chemical indicator cards did not reach the reference color; all biological indicators showed positive results after cultivation, with growth of *Bacillus stearothermophilus*. Under the condition of 140°C dry heat for 40 minutes: The indicator on the tested chemical indicator cards did not reach the reference color. Under the condition of 140°C dry heat for 38 minutes: The indicator on the tested chemical indicator cards did not reach the reference color. The positive control showed bacterial growth, while the negative control showed no bacterial growth. The results were consistent with the requirements of EN 867-5:2001 «Non-biological systems for use in sterilizers —Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S» .

2. Vacuum was drawn to 20 kPa, followed by steam injection to 95 kPa. This pulsing process was repeated 8 times. Saturated steam was then injected to reach the exposure temperature, which was maintained for the specified exposure time. After that, vacuum was drawn to 10 kPa, and air was injected to balance with atmospheric pressure. The test cycle 1 was run to conduct the performance test of the sterilization process challenge device (test passed). After 3 repeated tests, the chemical indicator cards used with the PRODONTO/OXEDRA Helix test PCD showed that the indicators on the tested cards reached the reference color under the following conditions: 15.0 minutes under 121°C saturated steam, 7.0 minutes under 128°C saturated steam, 3.5 minutes under 134°C saturated steam, and 3.0 minutes under 135°C saturated steam. The results were consistent with the requirements of EN 867-5:2001 «Non-biological systems for use in sterilizers —Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S» .

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3. Vacuum was drawn to 65 kPa, followed by steam injection to 95 kPa. This pulsing process was repeated 8 times. Saturated steam was then injected to reach the exposure temperature of 121°C and maintained for an exposure time of 15.0 minutes. Subsequently, saturated steam was injected to reach 128°C (maintained for 7.0 minutes), then 134°C (maintained for 3.5 minutes), and finally 135°C (maintained for 3.0 minutes). After that, vacuum was drawn to 10 kPa, and air was injected to balance with atmospheric pressure. Test cycle 2 was run to conduct the performance test of the sterilization process challenge device (test failed). After 3 repeated tests, the bacterial sheets inside the PRODONTO/OXEDRA Helix test PCD were inoculated and cultured in 3 bromocresol purple peptone liquid medium tubes, with the following results: Under 121°C saturated steam for 15.0 minutes: All 3 tubes showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under 121°C saturated steam for 7.5 minutes: All 3 tubes showed positive results after cultivation, with growth of *Bacillus stearothermophilus*. Under 128°C saturated steam for 7.0 minutes: All 3 tubes showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under 128°C saturated steam for 3.5 minutes: After cultivation, 1 tube was negative (no growth of *Bacillus stearothermophilus*) and 2 tubes were positive (with growth of *Bacillus stearothermophilus*). Under 134°C saturated steam for 3.5 minutes: All 3 tubes showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under 134°C saturated steam for 1.75 minutes: After cultivation, 1 tube was negative (no growth of *Bacillus stearothermophilus*) and 2 tubes were positive (with growth of *Bacillus stearothermophilus*). Under 135°C saturated steam for 3.0 minutes: All 3 tubes showed negative results after cultivation, with no growth of *Bacillus stearothermophilus*. Under 135°C saturated steam for 1.5 minutes: After cultivation, 1 tube was negative (no growth of *Bacillus stearothermophilus*) and 2 tubes were positive (with growth of *Bacillus stearothermophilus*). The positive control showed bacterial growth, while the negative control showed no bacterial growth. The results were consistent with the requirements of EN 867-5:2001 《Non-biological systems for use in sterilizers —Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S》.

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Authorized Signatory: 张子福

Final Review Date: October 16, 2025



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