

Tên trang thiết bị y tế: **Dây nội soi khí phế quản**

Model : EB11 - S01

Số công bố trang thiết bị y tế:

Số sê ri và NSX của trang thiết bị y tế: Xem trên nhãn chính

Nhà sản xuất: PENTAX Medical Bulgaria EOOD

Địa chỉ Nhà sản xuất: Vasil Levski str. 179. 4003 Plovdiv, BULGARIA.

Xuất xứ trang thiết bị y tế: BULGARIA

Đơn vị nhập khẩu và phân phối: **Công Ty TNHH xuất nhập khẩu y tế Thăng Long**




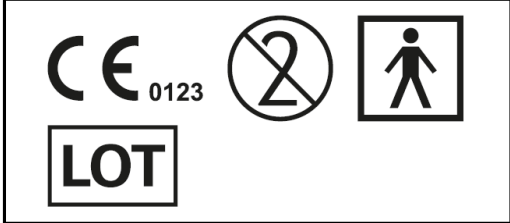
Địa chỉ: Lô 20-BT8 Khu Đô Thị Văn Quán – P.Văn Quán – Hà Đông, Hà Nội

Hotline: 0902177899/Tel/Fax:02423219979

Kỹ thuật: 0384 177 899 Web:thanglongmedical.com

Hướng dẫn sử dụng và Bảo quản, Cơ sở bảo hành: Xem sách hướng dẫn kèm theo

1. Labeling

Label No.	Labels
1	 <p>The image shows a label for a Pentax Medical instrument. The label is white with a dark grey bottom section. It features the text 'PENTAX MEDICAL' in red and black, and 'EB11-S01' in white on the dark grey background. A '1.2' is printed in white on a dark grey curved background in the top right corner. A line points from the text 'Model Name' to the 'EB11-S01' text. Another line points from the text 'Nominal instrument channel width' to the '1.2'.</p> <p>Model Name</p> <p>Nominal instrument channel width</p> <p>Description: To describe Model name(Catalog number), Nominal instrument channel width</p>
2	 <p>The image shows a rectangular box containing regulatory markings. On the left is the CE marking with '0123' below it. Below the CE marking is a box containing the word 'LOT'. To the right of the CE marking is a circle with a diagonal line through it and the number '2' inside. To the right of that is a square containing a stick figure.</p> <p>Description: To describe CE marking, Do not re - use, Batch Code, TYPE BF applied part</p>

Label No.	Labels
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3

Pentax Medical Single Use Video Bronchoscope

PENTAX MEDICAL Pulmo **ONE**

REF EB1X-S01  YYYY-MM-DD

LOT X2X4X6  YYYY-MM-DD



Distributors: **EC REP**
PENTAX Europe GmbH
Julius-Vosseler-Straße 104
22527 Hamburg, Germany

PENTAX Medical
A Division of PENTAX of America, Inc.
3 Paragon Drive, Montvale
NJ 07645-1782 USA

 60°C
 85%
 1060hPa
-20°C 10% 700hPa 

 **STERILE EO** **MD**

CE 0123 **Rx ONLY** Made in Bulgaria

Distributors:
PENTAX Shanghai Co., Ltd.
Room 701, 291 Fumin Road
Shanghai, 200031 P.R. China

PENTAX Medical Singapore Pte. Ltd.
438A Alexandra Road
#08-06 Alexandra Technopark
119967 Singapore

Manufacturer:
HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku
Tokyo 160-0023 Japan




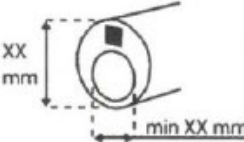
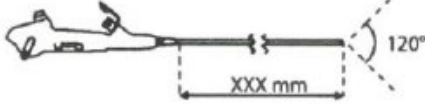












(01)12345678901234
(11)YYMMDD
(17)YYMMDD
(10)1234567

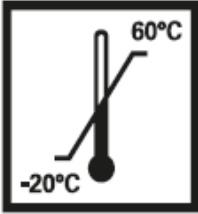





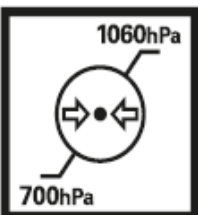










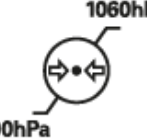


















(01)12345678901234(11)123456(17)123456(10)1234567

Description:
To describe Catalog number, Date of manufacture, Batch Code, Use - by date, Maximum insertion portion width, Minimum instrument channel width, Insertion portion working length, Field of view, Do not re – use, Do not re-sterilize, Type BF applied part, Do not use if package is damaged, Temperature limit, Humidity limitation, Atmospheric pressure limitation, Caution, Refer to instruction manual/booklet, Sterilized using ethylene oxide, Medical device in the EU, CE Marking, Rx ONLY statement, 2D bar code, 1D bar code and the address

LABEL No.	Labels
4	<div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;">Pentax Medical Single Use Video Bronchoscope</p> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  </div> <div style="text-align: center;"> <p>Pulmo ONE</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>REF EB1X-S01</p> <p>LOT X2X4X6</p> </div> <div style="width: 45%;"> <p> YYYY-MM-DD</p> <p> YYYY-MM-DD</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;">     </div> <div style="width: 45%;"> <p>Distributors:</p> <p>PENTAX Europe GmbH Julius-Vosseler-Straße 104 22527 Hamburg, Germany</p> <p>PENTAX Medical A Division of PENTAX of America, Inc. 3 Paragon Drive, Montvale NJ 07645-1782 USA</p> </div> <div style="width: 10%; text-align: center;"> <p>EC REP</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>60°C -20°C</p> <p>85% 10%</p> <p>1060hPa 700hPa</p>  </div> <div style="width: 45%;"> <p>PENTAX Shanghai Co., Ltd. Room 701, 291 Fumin Road Shanghai, 200031 P.R. China</p> <p>PENTAX Medical Singapore Pte. Ltd. 438A Alexandra Road #08-06 Alexandra Technopark 119967 Singapore</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;">  <p>STERILE EO</p>  <p>MD</p> <p>CE 0123 Rx ONLY Made in Bulgaria</p> </div> <div style="width: 45%;"> <p>Manufacturer: HOYA Corporation 6-10-1 Nishi-shinjuku, Shinjuku-ku Tokyo 160-0023 Japan</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;">  <p>(01)12345678901234 (11)YYMMDD (17)YYMMDD (10)1234567</p> </div> <div style="width: 45%;">  <p>(01)12345678901234(11)123456(17)123456(10)1234567</p> </div> </div> </div>
	<p>Description:</p> <p>To describe Catalog number, Date of manufacture, Batch Code, Use - by date, Maximum insertion portion width, Minimum instrument channel width, Insertion portion working length, Field of view, Packaging unit, Do not re – use, Do not re-sterilize, Type BF applied part, Do not use if package is damaged, Temperature limit, Humidity limitation, Atmospheric pressure limitation, Caution, Refer to instruction manual/booklet, Sterilized using ethylene oxide, Medical device in the EU, CE Marking, Rx ONLY statement, 2D bar code, 1D bar code and the address</p>

Label No.	Labels	Description	Label No.	Labels	Description
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5		Temperature limit	5		Stacking limitation
5		Store with this side upwards	5		Keep away from rain
5		Fragile; handle with care	5		Humidity limitation
5		Atmospheric pressure limitation	6		General symbol for recovery/recyclable

LABEL No.	Labels			
7	<div style="text-align: center;"> <p>Pentax Medical Single Use Video Bronchoscope</p>   </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p>-20°C 60°C</p> </div> <div style="text-align: center;">  <p>10% 85%</p> </div> <div style="text-align: center;">  <p>700hPa 1060hPa</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;">      </div>			
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> Pentax Item No. EB1X-S01 </td> <td style="width: 10%; text-align: center; padding: 5px;"> <div style="border: 1px solid black; padding: 2px;">REF</div> </td> <td style="width: 40%; padding: 5px;"> Quantity 20  </td> </tr> </table>	Pentax Item No. EB1X-S01	<div style="border: 1px solid black; padding: 2px;">REF</div>	Quantity 20 
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	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; text-align: center; padding: 5px;">  </td> <td style="width: 35%; padding: 5px;"> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black;"> EC REP </div> <p>Distributor: PENTAX Europe GmbH Julius-Vosseler-Straße 104 22527 Hamburg, Germany</p> </td> <td style="width: 35%; padding: 5px;">  <p>Manufacturer HOYA Corporation 6-10-1 Nishi-shinjuku, Shinjuku-ku Tokyo 160-0023 Japan</p> </td> </tr> </table>		<div style="display: flex; justify-content: space-between; border-bottom: 1px solid black;"> EC REP </div> <p>Distributor: PENTAX Europe GmbH Julius-Vosseler-Straße 104 22527 Hamburg, Germany</p>	 <p>Manufacturer HOYA Corporation 6-10-1 Nishi-shinjuku, Shinjuku-ku Tokyo 160-0023 Japan</p>
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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%; padding: 5px;"> Item Description Single Use Video Bronchoscope </td> <td style="width: 40%; padding: 5px;"> Expiration Date YYYY-MM-DD  </td> </tr> </table>	Item Description Single Use Video Bronchoscope	Expiration Date YYYY-MM-DD 		
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<div style="text-align: center;">  <p>(01)12345678901234(11)123456(17)123456(10)1234567</p> </div>				
<p>Description: To describe Do not use if package is damaged, Do not re – use, CE Marking, Temperature limit, Humidity limitation, Atmospheric pressure limitation, Keep away from rain, Fragile; handle with care, General symbol for recovery/recyclable, Store with this side upwards, Stacking limitation, Catalog number, Packaging unit, Refer to instruction manual/booklet, the address, Use - by date, Batch Code and 1D bar code</p>				