

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

Model : EB15 - 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 with a white background and a dark grey bottom section. The top part contains the text 'PENTAX MEDICAL' in red and black. Below that is 'EB15-S01' in white on the dark grey background. A dark grey semi-circle on the right side contains the number '3.0'. A line points from '3.0' to the text 'Nominal instrument channel width' on the right. Another line points from 'EB15-S01' to the text 'Model Name' on the left.</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 several symbols: 'CE' with '0123' to its right, a 'LOT' in a box, a '2' in a circle with a diagonal line through it, and a person icon in a square.</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

 **STERILE EO** **MD** PENTAX Shanghai Co., Ltd.
Room 701, 291 Fumin Road
Shanghai, 200031 P.R. China

CE ₀₁₂₃ **Rx ONLY** Made in Bulgaria PENTAX Medical Singapore Pte. Ltd.
438A Alexandra Road
#08-06 Alexandra Technopark
119967 Singapore




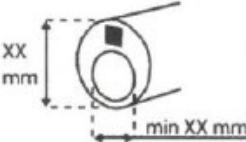
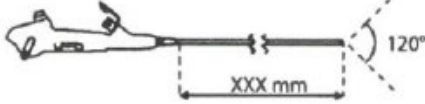










 (01)12345678901234
(11)YYMMDD
(17)YYMMDD
(10)1234567

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

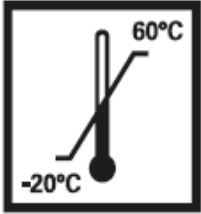





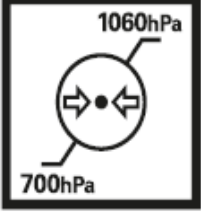



(01)12345678901234(11)123456(17)123456(10)1234567

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>Distributors:</p> <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> <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>STERILE EO</p>  <p>MD</p> <p>CE 0123 Rx ONLY Made in Bulgaria</p> </div> <div style="width: 45%;"> <p>(01)12345678901234 (11)YYMMDD (17)YYMMDD (10)1234567</p> </div> </div> <div style="text-align: center; margin-top: 10px;">   <p>(01)12345678901234(11)123456(17)123456(10)1234567</p> </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.











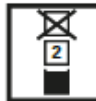
Labels






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Pentax Medical Single Use Video Bronchoscope

PENTAX
MEDICAL

Pulmo
ONE

Pentax Item No. EB1X-S01	REF	Quantity 20	
	EC REP Distributor: PENTAX Europe GmbH Julius-Vosseler-Straße 104 22527 Hamburg, Germany	 Manufacturer: HOYA Corporation 6-10-1 Nishi-shinjuku, Shinjuku-ku Tokyo 160-0023 Japan	
Item Description Single Use Video Bronchoscope	Expiration Date YYYY-MM-DD		
Lot Nr. or Serial No. X2X4X6	LOT	Pentax Purchase Order No.	
 (01)12345678901234(11)123456(17)123456(10)1234567			

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