



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA  
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

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Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

**NOMOR IZIN EDAR**

**ALAT KESEHATAN**

**KEMENKES RI AKL 21502914073**

Nama Dagang / Merek : **ANZAI Respiratory Gating System**  
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / C  
Kategori Produk : Peralatan Radiologi  
Sub Kategori : Peralatan Radiologi Terapetik  
Jenis Produk : Medical charged-particle radiation therapy system.  
Tipe / Ukuran : Tipe AZ-733VI  
Kemasan : -  
Nama Produsen / Pabrikan : ANZAI MEDICAL CO., LTD, Japan  
Nama Pendaftar : PT. SIEMENS INDONESIA, DKI Jakarta  
Atas dasar lisensi dari : -

**Ketentuan**

1. Persetujuan izin edar berlaku sampai dengan 15 Februari 2024.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.




**Jakarta, 01 Juli 2019**






**Catatan:**


- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
- Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.


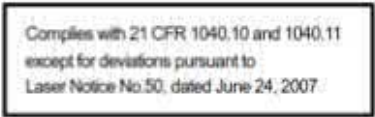
**PENANDAAN ANZAI Respiratory Gating System**

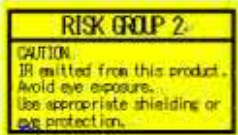
Label	Location
<div data-bbox="360 462 902 916" style="border: 1px solid black; padding: 5px;"> <p>Product Name : Respiratory Gating System                      Model : AZ-733VI                      Power Supply : AC100-240V~                      Frequency : 50/60Hz                      Power Input : 80-120VA                      Classification : I</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>SN</b> _____</p> <p><b>LOT</b> _____</p> </div> <div style="width: 45%; text-align: center;">      <p><b>ANZAI MEDICAL CO., LTD.</b>                      3-9-15 Nishi-Shinagawa, Shinagawa-ku,                      Tokyo,141-0033, Japan</p> <p><b>MADE IN JAPAN</b></p> </div> </div> </div> <p align="center"><b>Main Unit Label</b></p>	<p>On the rear side of the Sensor Port</p>

Label	Location															
<div data-bbox="263 1171 1084 1830" style="border: 2px solid black; padding: 10px;"> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;"> <p><i>Respiratory Gating System</i></p> <p><b><u>AZ-733VI</u></b></p> </div> </div> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p><b>SN</b> : _____ :20 - -</p> </div> <div style="text-align: center; margin: 10px 0;">  <p><b>Anzai Medical Co., Ltd.</b>                      3-9-15 Nishi-Shinagawa Shinagawa-ku, Tokyo Japan                      TEL: +81-3-3779-2571 FAX: +81-3-3779-2573</p> </div> <div style="display: flex; justify-content: space-between; align-items: center; margin: 10px 0;"> <div style="border: 1px solid black; padding: 2px;"> <p><b>EC REP</b></p> </div> <div style="text-align: center;"> <p><b>Advena Ltd.</b>                      Tower Business Centre, 2<sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta</p> </div> <div style="text-align: center;">  </div> </div> <table border="1" style="width: 100%; font-size: small; margin: 10px 0;"> <thead> <tr> <th></th> <th align="center">Transport</th> <th align="center">Storage</th> </tr> </thead> <tbody> <tr> <td>a) An ambient temperature range</td> <td align="center">-40 ~ +60 °C</td> <td align="center">-10 ~ +60 °C</td> </tr> <tr> <td>b) A relative humidity range</td> <td align="center">10 ~ 90%</td> <td align="center">10 ~ 90%</td> </tr> <tr> <td></td> <td align="center">Non Condensing</td> <td align="center">Non Condensing</td> </tr> <tr> <td>c) An atmospheric pressure range</td> <td align="center">500 ~ 1060hPa</td> <td align="center">500 ~ 1060hPa</td> </tr> </tbody> </table> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p><b>Packing article</b></p> <p><input type="checkbox"/> Main Unit</p> <p><input type="checkbox"/> Personal Computer</p> <p><input type="checkbox"/> System Cables</p> <p><input type="checkbox"/></p> </div> </div> <p align="center"><b>Box Label</b></p>		Transport	Storage	a) An ambient temperature range	-40 ~ +60 °C	-10 ~ +60 °C	b) A relative humidity range	10 ~ 90%	10 ~ 90%		Non Condensing	Non Condensing	c) An atmospheric pressure range	500 ~ 1060hPa	500 ~ 1060hPa	<p>On the top of the packing box</p>
	Transport	Storage														
a) An ambient temperature range	-40 ~ +60 °C	-10 ~ +60 °C														
b) A relative humidity range	10 ~ 90%	10 ~ 90%														
	Non Condensing	Non Condensing														
c) An atmospheric pressure range	500 ~ 1060hPa	500 ~ 1060hPa														



Label	Contents	Location
 <p>The label features a yellow warning triangle with an exclamation mark at the top. Below it, the word "CAUTION" is written in bold. Three bullet points follow: "No need to wind it on a patient's skin directly.", "Ne fixez pas la ceinture de fixation directement sur la peau du patient", and "直接地肌に巻かない事。". Below the text are two diagrams showing a person's back with a belt; the first diagram has a red 'X' over it, and the second has a red circle with a slash. At the bottom left is the ANZAI logo, and at the bottom right, it says "Load Cell Fixing Belt", "P/N : 400073 - 8", and "Size : S".</p> <p>Caution Label</p>	<p>No need to wind it on a patient's skin directly.</p>	<p>On the Load Cell Fixing Belt</p>

Label	Contents	Location
 <p>The label is yellow with a black border. It features a laser warning symbol (a triangle with a dot) on the left. The text reads: "LASER APERTURE" with an arrow pointing left, "LASER RADIATION DO NOT STARE INTO BEAM", "MAXIMUM OUTPUT 1mW", "PULSE DURATION 2ms Max", "WAVELENGTH 650nm", "CLASS2 LASER PRODUCT (IEC60825-1:2007)".</p> <p>Laser Warning Label</p>	<p>LASER RADIATION DO NOT STARE INTO BEAM CLASS2 LASER PRODUCT</p>	<p>On the Laser Sensor Head</p>
 <p>The label is white with a black border and contains the text: "Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated June 24, 2007".</p> <p>Laser Compliance Label</p>	<p>The statement of compliance with FDA performance standards for laser products.</p>	<p>On the Laser Sensor Head</p>

Label	Contents	Location
 <p>The label is yellow with a black border. It says "RISK GROUP 2" in bold, followed by "CAUTION IR emitted from this product. Avoid eye exposure. Use appropriate shielding or eye protection."</p> <p>RISK GROUP2 Label</p>	<p>RISK GROUP2 LED PRODUCT. IR emitted from this product. Avoid eye exposure. Use appropriate shielding or eye protection.</p>	<p>On the top of the IRP Sensor Main Unit</p>



Label	Contents	Location
<p><b>CAUTION</b></p> <ul style="list-style-type: none"> <li>• Be sure to confirm this cable is Securely connected before use of the system.</li> <li>• Be sure not to allow this cable disconnected from AC adapter during use of the system.</li> </ul> <p>AC Power Cable Label</p>	<ul style="list-style-type: none"> <li>• Be sure to confirm this cable is Securely connected before use of the system.</li> <li>• Be sure not to allow this cable disconnected from AC adapter during use of the system.</li> </ul>	On the AC Power Cable

Product Name	: Anzai Breath Learning Equipment	
Model	: ABLE	
Power Supply	: DC+12V	
Power Input	: 0.80W	
Classification	: I	
SN	_____	
LOT	_____	
		<b>ANZAI MEDICAL CO., LTD.</b> 3-9-15 Nishi-Shinagawa, Shinagawa-ku, Tokyo, 141-0033, Japan <b>MADE IN JAPAN</b>

Rating Label of Bluetooth Transceiver

**Diproduksi oleh:**  
 Anzai Medical Co., Ltd., Japan  
 3-9-15 Nishi-Shinagawa, Shinagawaku  
 Tokyo 141-0033, Japan

**Diimpor oleh:**  
 PT Siemens Indonesia  
 Jl. Jend. Ahmad Yani No.2 Kav 67-68  
 Jakarta, Indonesia

**KEMENKES RI AKL**





Foto produk

