

**Product Name: Medical Disposable Protective Clothing (PC002)**

**Description:**

<b>Type:</b>	<b>One-Piece</b>
<b>Standard:</b>	<b>FDA / CE / GB 19082 - 2009</b>
<b>Application:</b>	<b>Hospitals, and many more places</b>
<b>Function:</b>	<b>The product is intended to be used as protective clothing providing protection against infective agents.</b>

**Product & Packing Photo:**

**Size Chart:**

Type	160	165	170	175	180	185	Tolerance
	S	M	L	XL	XXL	XXL	
<b>Length</b>	165	169	173	178	181	188	± 2
<b>Chest</b>	120	125	130	135	140	145	± 2
<b>Arm Length</b>	84	86	90	93	96	99	± 2
<b>wrist</b>	<b>18</b>						

**Product Photo:**



**Certificate:**

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">CERTIFICATE ◆ ZERTIFIKAT ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE</p>	 <p><b>Fiscal Year 2020 CERTIFICATION OF REGISTRATION</b></p> <p>This certifies that:</p> <p>has completed the FDA Establishment Registration (as Manufacturer) and Device Listing with the US Food &amp; Drug Administration, through</p> <p>U.S. Agent for FDA Communications:</p> <p><b>Registration Number: 3013496867</b> <b>Device Listing#: See annex</b></p> <p><small>Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.</small></p> <p><small>Pursuant to 21 CFR 807.59, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.</small></p>  	<p>防护服 File No: CE-MDR-TCF001-01</p> <p><b>CE</b> EC Declaration of Conformity <b>CE</b> Regarding Medical Device Regulation (EU) 2017/745</p> <p>Manufacturer:</p> <p>European Authorized Representative: Name: Address: Netherlands</p> <p>Product: Name: Protective Suit Model: 160, 165, 170, 175, 180, 185 or customized</p> <p>Classification: I Rule: According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU)2017/745.</p> <p>SRN: - UDI: -</p> <p>Conformity Assessment Route: Annex II&amp;III in Medical Device Regulation (EU 2017/745)</p> <p>We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards: EN ISO 13485:2016/EN ISO 14971:2012 EN ISO 15223-1:2016 / EN 1041:2008 ISO 10993-1:2018 / EN ISO 10993-5:2009 / EN ISO 10993-10:2010 EN ISO13982-1: 2011 / EN ISO13982-2: 2004 EN ISO13034: 2013 / EN ISO 17491-4: 2008 EN 14325: 2018 / IEC 62366-1:2015</p> <p>Signature: <i>Jerry</i> Date: 2020/12/14</p> 
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