

Medical Device Registration App. Form	
Trade Name	<p>PulsioFlex Monitor</p> <ul style="list-style-type: none"> <li>Write name exactly as it Appears on device and promotional material.</li> </ul>
Generic Name	<p>Invasive arterial pressure cardiac output/oximetry monitor</p> <ul style="list-style-type: none"> <li>Generic name is composed of a core word and generally no more than three feature words. The core word is a generalized expression for medical devices with the same or similar technical principles, structure or intended use. The feature word is a description of the specific attribute of the medical device, such as the site of application in/to the body, structural feature, technical feature or material composition.</li> <li>Generic name <b>should not</b> contain the following: trade name, model name, symbols, claims or assurances on the effectiveness, Exaggerated claims.</li> </ul>
Device Type	<p>Device</p> <ul style="list-style-type: none"> <li>Select from List (Device, Equipment, Consumable, etc.)</li> </ul>
Device Scope	<p>Vital signs monitoring</p> <ul style="list-style-type: none"> <li>The area of specialty that medical device deals with or to which it is relevant.</li> </ul>
Device Specifications	<p>The PulsioFlex housing consists of an aluminum die cast with plastic bottom plate and a plastic display frame. The size of the PulsioFlex is 216 mm x 177 mm x 127 mm (W x H x D), with a total weight of 1.8 kg. The hardware components are spread out on the following four different printed circuit boards (PCB): Display PCB, CPU PCB, AFE PCB, Baseboard PCB</p> <ul style="list-style-type: none"> <li>Briefly Mention the following: <ul style="list-style-type: none"> <li>Material,</li> <li>Dimensions,</li> <li>Performance attributes,</li> <li>And any related information that would typically appear in promotional materials.</li> </ul> </li> </ul>
Intended Use	<p>Diagnostic aid for the minimally invasive Measurement and monitoring of blood pressure, cardiopulmonary, circulatory and organ function variables.</p> <ul style="list-style-type: none"> <li>The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.</li> </ul>

<b>Classification According to Country of Origin</b>	<b>IIb</b> <ul style="list-style-type: none"> <li>■ Medical devices are classified into four classes (A, B, C, D), (I, Im, Is, IIa, IIb, III), or (I, II, II with special controls, III) based on degree of risk with class (A, I) being the lowest risk and Class (D, III) devices having the highest risk.</li> <li>■ The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technology/ies it utilizes.</li> <li>■ <b>Classification is the responsibility of the manufacturer only.</b></li> </ul>
<b>Size Volume</b>	216 mm x 177 mm x 127 mm <ul style="list-style-type: none"> <li>■ Size unit should be clarified.</li> </ul>
<b>Model Catalog No Ref No</b>	<b>PC4000</b> <ul style="list-style-type: none"> <li>■ Model, Catalog No, or Ref No depends on the type of medical device.</li> <li>■ It should be written as it appears in technical information, quality certificates, label, and shipping documents.</li> </ul>
<b>Poison Or Medicine</b>	<b>No</b> <ul style="list-style-type: none"> <li>■ Whether the medical device incorporates a medicinal substance(s) or not. If yes, the attached technical info. should provide detailed information concerning that medicinal substance, its identity and source, the intended reason for its presence, and its safety and performance in the intended application.</li> </ul>
<b>Description</b>	A mains electricity (AC-powered) device designed to continuously measure arterial pressure cardiac output (APCO) [minimally-invasive cardiac output estimation from arterial blood pressure waveforms] and oxygen saturation (oximetry) when connected to an extravascular blood pressure transducer and an oximetry catheter. In addition, it may also calculate other parameters including cardiac index, stroke volume, stroke volume index, stroke volume variation, and system vascular resistance. It is typically used in the operating arena or the intensive care unit (ICU) <ul style="list-style-type: none"> <li>■ Briefly Mention the following: <ul style="list-style-type: none"> <li>- <i>Intended patient population,</i></li> <li>- <i>Novel features,</i></li> <li>- <i>Accessories,</i></li> <li>- <i>Functional elements/parts.</i></li> </ul> </li> </ul>

<b>Category</b>	<b>Moderate to high Risk</b> <ul style="list-style-type: none"> <li>■ Select from list.</li> <li>■ Medical devices “<b>in Sudan</b>” are classified into four classes A, B, C, D based on degree of risk with class A being the lowest risk and Class D devices having the highest risk.</li> </ul>
<b>Shelf Life</b>	<b>96</b> <ul style="list-style-type: none"> <li>■ Number should be written in months</li> <li>■ For devices and equipments, this means life span, which is an indication to the typical age of biomedical device in which it is expected to be effective and safe for its intended use, under normal operating circumstances.</li> <li>■ For consumables and solutions, it is the length of time in which a commodity may be stored without becoming unfit for its intended use, consumption, and sale.</li> </ul>
<b>GMDN Code</b>	<b>42873</b> <ul style="list-style-type: none"> <li>■ (GMDN) Global Medical Device Nomenclature is a system of internationally agreed descriptors used to identify medical device products. The GMDN Database lists all the terms, which are currently available to name and describe medical devices,</li> <li>■ How can I get a GMDN Code for my product? Only GMDN Membership (<b>Manufacturers</b>) can give you access to the GMDN Codes. After joining the GMDN Terms and Codes are found on our website using a simple search tool.</li> </ul>
<b>technology Category</b>	<b>Medium Technology</b> <ul style="list-style-type: none"> <li>■ Select from list</li> <li>■ This is related to registration fees, you will find a list of categories in the website.</li> </ul>