



1. ADMINISTRATIVE INFORMATION OF THE COMPANY		Last update : 23/01/2019						
1.1	Name : BodyCAP							
1.2	Adresse : 3 rue du Docteur Laënnec 14200 Hérouville St Clair – France	Tel : 33 (0)2 61.53.03.29 E-Mail: contact@bodycap-medical.com Website : www.bodycap-medical.com						
2. INFORMATION ON THE EQUIPMENT								
2.1	Common name : Core temperature monitoring system							
2.2	Commercial name : e-Celsius Performance activator							
2.3	Manufacturer of the equipment : BodyCAP							
2.4	<p><b>DESCRIPTION OF THE EQUIPMENT (WITH PICTURES, SCHEMA, DIMENSIONS, ...)</b> :</p> <p><u>e-Celsius Performance activator</u> :</p> <p>The activator is intended to activate a capsule e-Celsius® Performance before a measurement cycle.</p> <p>Dimension : 69 mm x 59 mm x 31 mm</p> 							
2.5	<p><b>CATALOGUE REFERENCE:</b></p> <table border="1" style="width: 100%;"> <thead> <tr> <th>REFERENCE</th> <th>DESIGNATION</th> </tr> </thead> <tbody> <tr> <td>EPERF_ACTIVATOR</td> <td>e-Celsius® Performance activator (including USB cable with ferrite)</td> </tr> </tbody> </table> <p>Order unit : 1 Minimum delivery quantity : 1</p> <p><b>LABELLING :</b></p> 		REFERENCE	DESIGNATION	EPERF_ACTIVATOR	e-Celsius® Performance activator (including USB cable with ferrite)		
REFERENCE	DESIGNATION							
EPERF_ACTIVATOR	e-Celsius® Performance activator (including USB cable with ferrite)							
2.6	<p><b>COMPOSITION OF THE EQUIPMENT :</b></p> <p>The activator e - Celsius® Performance has the role of 'wake up' the capsule.</p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Components</th> <th>Raw Material</th> </tr> </thead> <tbody> <tr> <td>Plastic</td> <td>Grained polycarbonate</td> </tr> <tr> <td>Primary packaging</td> <td>Box with cushioning foam</td> </tr> </tbody> </table>		Components	Raw Material	Plastic	Grained polycarbonate	Primary packaging	Box with cushioning foam
Components	Raw Material							
Plastic	Grained polycarbonate							
Primary packaging	Box with cushioning foam							

2.7	<p><u>DOMAIN - INDICATION :</u></p> <p>e-Celsius® Performance, swallowed pill, allow to measure, record and continuously follow the core temperature of a subject.</p> <p>The main application are :</p> <ul style="list-style-type: none"> <li>- <b>Reduce the risk</b> for people in extreme situation, as high-level athletes or workers in restrictive environments (firemen, military). Indeed, in case of effort in hot atmosphere, heat stress is amplified by the environmental temperature and humidity. The saturation of the thermal regulation system is a risk of nausea, fainting or death.</li> <li>- <b>-Optimize the performance of the athletes.</b> Once ingested, the capsule leaves the athlete free of his movements. It allows the continuous recording of the temperature during warm-up, competition as well as during the recovery phase. The resulting data allow to better understand the relationship between thermoregulation and performance and thus to maximize and individualize the training protocols for each athlete.</li> </ul> <p>All sports are concerned, but particularly the sports that require an supported and extended effort as cycling, long-distance running, triathlon, rugby or those taking place in special thermal conditions as diving.</p> <p><b>Use case :</b></p> <ul style="list-style-type: none"> <li>→ Hypothermia/Hyperthermia prevention</li> <li>→ Warm up – recovery process optimization</li> <li>→ Performance assessment/optimization</li> <li>→ Preventing, quantifying and avoid the Jet-Lag issue</li> <li>→ Sleep, circadian rhythms and athletic performances analysis</li> </ul>
<b>3. STERILIZATION PROCESS :</b>	
	<p>Sterile device : NA</p> <p>Mode of sterilization of the device : NA</p>
<b>4. CONSERVATION AND STORAGE CONDITIONS</b>	
	Store dry and at room temperature. Do not expose to organic solvents, ionizing radiation, or UV light.
<b>5. SAFETY OF USE :</b>	
5.1	<b>Technical security:</b> consult the manual of use
5.2	<b>Biological security:</b> consult the manual of use
<b>6. CONDITION OF USE :</b>	
6.1	<b>Use :</b> refer to the user manual supplied with each monitor
6.2	<b>Indications:</b> See above § 2.8
6.3	<b>Precautions of use:</b> refer to the manual of use
6.4	<b>Contraindication :</b> consult the manual of use