


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-Viewer® Performance monitor							
2.4	Manufacturer : BodyCAP							
2.5	<p>DESCRIPTION OF THE EQUIPMENT (WITH PICTURES, SCHEMA, DIMENSIONS, ...) :</p> <p><u>e-Viewer® Performance monitor :</u></p> <p>3 pills per monitor Multichannel: 7 monitors in parallel Storage: 80 000 data by capsule Autonomy : 36h Dimension : 120mm x 70mm x 15mm Telemetry communication (433-434 MHz)</p>							
2.6	<p><u>CATALOGUE REFERENCE:</u></p> <table border="1"> <thead> <tr> <th>REFERENCE</th> <th>DESIGNATION</th> </tr> </thead> <tbody> <tr> <td>KIT_EPERF_CE</td> <td>e-Viewer® Performance monitor (including USB cable, protection pouch without software)</td> </tr> <tr> <td>KIT_EPERF_CE-SW</td> <td>e-Viewer® Performance monitor (including USB cable, protection pouch and software)</td> </tr> </tbody> </table> <p>Order unit : 1 Minimum delivery quantity : 1</p> <p><u>LABELLING :</u></p> 		REFERENCE	DESIGNATION	KIT_EPERF_CE	e-Viewer® Performance monitor (including USB cable, protection pouch without software)	KIT_EPERF_CE-SW	e-Viewer® Performance monitor (including USB cable, protection pouch and software)
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2.7	<p><u>COMPOSITION OF THE EQUIPMENT :</u></p> <p>- e-Viewer® performance monitor is designed to collect the data collected by e-Celsius Performance pills. It is delivered with USB cable, protection pouch, documentation and software</p>							



	(if ordered at the order)						
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2.8	<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"> - Reduce the risk 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. - -Optimize the performance of the athletes. 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. <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>Use case :</p> <ul style="list-style-type: none"> → Hypothermia/Hyperthermia prevention → Warm up – recovery process optimization → Performance assessment/optimization → Preventing, quantifying and avoid the Jet-Lag issue → Sleep, circadian rhythms and athletic performances analysis 						
3. STERILIZATION PROCESS :							
	<p>Sterile device : NA</p> <p>Mode of sterilization of the device : NA</p>						
4. CONSERVATION AND STORAGE CONDITIONS							
	Store dry and at room temperature. Do not expose to organic solvents, ionizing radiation, or UV light.						
5. SAFETY OF USE :							
5.1	Technical security: consult the manual of use delivered with each monitor						
5.2	Biological security: consult the manual of use delivered with each monitor						
6. CONDITION OF USE :							
6.1	Use : refer to the user manual supplied with each monitor						
6.2	Indications: See above § 2.8						
6.3	Precautions of use: refer to the manual of use supplied with each monitor						
6.4	Contraindication : consult the manual of use supplied with each monitor						