



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 pill	
2.3	Manufacturer of the equipment : BODYCAP	
2.4	<p>DESCRIPTION OF THE EQUIPMENT (WITH PICTURES, SCHEMA, DIMENSIONS, ...):</p> <p>e-Celsius® Performance, swallowed pill, allowing to measure, record and continuously follow the core temperature of a subject.</p> <p><u>e-Celsius Performance pill :</u></p> <p>Storage : Up to one year Weight: 1.7g Size: 17.7mm x 8.9 mm Sampling: 10s, 30s, 1min, 2min, 5min Accuracy: 0.2°C Operational range: 25°C to 45°C Store up to 2000 data Wireless transmission (433 MHz) Communication range: 1 m Operational duration: 20 days</p> <p>Each pill is delivered with a « No IRM » wristband</p> <p><u>« No IRM » wristband :</u></p> <p>Identification wristband allowing to report the ingestion of a capsule by the subject. In this context, it is formally forbidden that the patient is submitted to a MRI.</p>	
		
		

CATALOGUE REFERENCE :

REFERENCE	DESIGNATION
CAPSULE_ECP	e-Celsius® Performance pill
Bracelet_IRM	« No IRM » wristband

2.5

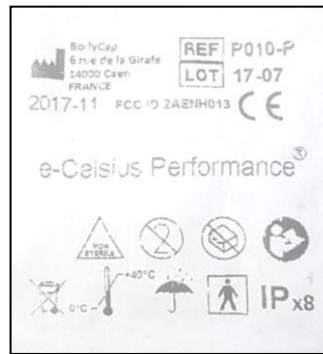
The capsules are conditioned unitarily under blister bag:

The e-Celsius® Performance pill is a single use pill, delivered NON STERILE.

Order unit : 1

Minimum delivery quantity : 1

LABELLING :



2.6

COMPOSITION OF THE EQUIPMENT :

All materials used for the manufacture of the product are biocompatible.

Components	Raw material
Capsule	Free PVC
Primary packaging	Blister bag

The capsule has no effect for the digestive system since she left after one to two days, a period that depends on the time of transit.

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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"> - 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 :	
Sterile device : NA	
Mode of sterilization of the device : NA	
4. CONSERVATION AND STORAGE CONDITIONS	
Store dry and at room temperature. Do not expose to organic solvents, ionizing radiation, or UV light. Shelf life of the product: 1 year	
5. SAFETY OF USE :	
5.1	Technical security: consult the manual of use
5.2	Biological security: consult the manual of use
6. CONDITION OF USE :	
6.1	Use : refer to the user manual
6.2	Indications: See above § 2.8
6.3	Precautions of use: refer to the manual of use
6.4	Contraindication : consult the manual of use