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	<b>Declaration of Conformity according to AMF-PPE EU 2016/425</b> <b>Product: Green Polly</b>		<b>01</b>	<b>1(3)</b>
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## Declaration of Conformity

### 1. Purpose

A supplier or importer of a CE marked product used for personal protective equipment according to EU 2016/425 needs to establish a technical file and a declaration of conformity.

### 2. Scope

The following articles are included for this declaration of conformity:

Article Number	Product Name	Declaration of conformity, Class
650001	Green Polly	This DOC is specified for a Class 1 Personal Protective Equipment (PPE) for the apron product Green Polly

This declaration of conformity covers both conformity against AMF requirements EU 2016/425 and its relevant transposition into national laws of the member states into which we place the devices.

Cellcomb AB is exclusively responsible for the declaration of conformity.


### 3. Intended use

For protection against dirt, water and liquids. Increased hygiene protection for caregivers.

### 4. Declaration of Conformity according to Class 1 personal protective equipment 2016/425

Category 1 Requirement	Conforms (Y/N)	Reference
Withstands Light mechanical damage	Yes	Production quality control by manufacturer. Instruction for use describes to make quality production control prior to use according to
Contact with weak cleaning solutions and detergents.	Yes	

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<b>Signature:</b> Camilla Collin	<b>Approval date:</b> 2021-03-15	<b>Effective date:</b> 2021-03-15

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Withstand long contact with water.		
Contact with surfaces that is warmer than 50 °C.	Yes	The air temperature suitable for using the apron is + 5 to +40 degrees Celsius.
Lowering the risk of contamination of patients	Yes	This claim is supported by scientific literature and similar benchmarked products consisting of laminated polyethylene. Ref Clinical evaluation report Green Polly.
Serves as an extra barrier against liquids such as water, ethanol, blood, mild chemicals and detergents.	Yes	This claim is supported by scientific literature and similar benchmarked products consisting of laminated polyethylene that withstand a barrier property towards mild chemicals. Ref Clinical evaluation report Green Polly.
Increases hygiene	Yes	This claim is supported by scientific literature and similar benchmarked products consisting of laminated polyethylene. Ref Clinical evaluation report Green Polly.
Disposable, single use	Yes	The instructions to user clearly states that the device is a disposable, single use device.
Damage to eyes following due to exposure to sunlight	Not applicable (N/A) Product to be used indoors	Not applicable (N/A) Product to be used indoors
Weather conditions not consisting of extreme charactor	Not applicable (N/A) Product to be used indoors	Not applicable (N/A) Product to be used indoors

We, the manufacturer, hereby declare that the above mentioned products comply with the EU 2016/425, and its relevant transposition into national laws of the member states into which we place the devices.

Cellcomb AB is exclusively responsible for the declaration of conformity.


Date:



Martin Lundqvist, CEO Cellcomb AB

Name and authority (CEO)

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## 5. References

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