



Quality Solutions With You Every Step

## **Product compliance:**

- Libre Shield Armband 3 – Black color
- Libre Shield Armband 2 – Black color
- Libre Shield Armband 2 – Purple color
- Libre Shield Armband 2 – Aquarius color

## **Technical report according to GPSR**

Prepared for Project604 Research Inc.

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Commercial In Confidence

This report is confidential and subject to the condition that it may not be disclosed in whole or in part to others without the written consent of HQTS

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## **1. Introduction**

According to article 9 of GPSR REGULATION (EU) 2023/988, before placing their products on the market, manufacturers shall carry out an internal risk analysis and draw up technical documentation containing at least a general description of the product and its essential characteristics relevant for assessing its safety. Where appropriate with regard to possible risks related to the product, the technical documentation referred to in the first subparagraph shall also contain, as applicable:

- (a) An analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any reports related to tests conducted by the manufacturer or by another party on their behalf (please consult the risk assessment report).
- (b) The list of any relevant European standards as referred to in Article 7(1), point (a), or the other elements referred to in Article 7(1), point (b) or Article 8, applied to meet the general safety requirement laid down in Article 5.

Where any of the European standards, health and safety requirements or elements as referred to in Article 7(1) or Article 8 have been only partly applied, the manufacturers shall identify the parts which have been applied.

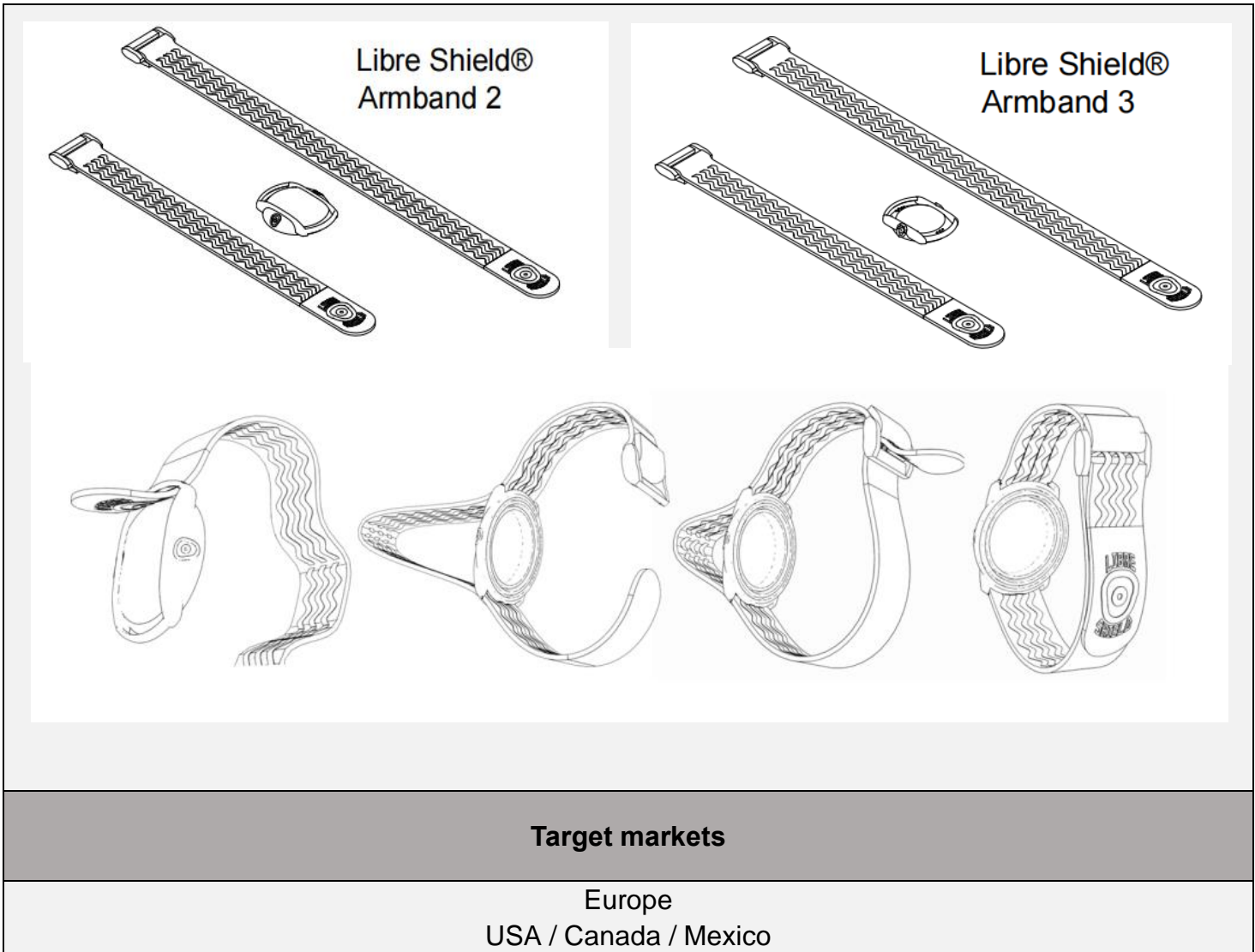
Manufacturers shall ensure that the technical documentation referred to in paragraph 2 is up to date. They shall keep that documentation at the disposal of the market surveillance authorities for a period of 10 years after the product has been placed on the market and make that documentation available to those authorities upon request.

**Note:**

This technical documentation is made to ensure the compliant with **EU GPSR**.

## 2. Product information and target market

Product name
<p>Libre Shield Armband 3 – Black color          Libre Shield Armband 2 – Black color / Purple color / Aquarius color</p>
Product description
<p>It is made of medical-grade silicone, specially designed for the FreeStyle Libre 2 /3 sensor, which can provide the maximum level of waterproof protection and skin grip. No adhesive patches are needed. It has two anti-slip, multi-size adjustable armbands to ensure a firm and comfortable fit. It is suitable for the FreeStyle Libre 14-Day Sensor continuous glucose monitor. It is washable and reusable.</p>
Intended use
<p>The Libre Shield Armband 2 / 3 is intended for use as a body worn travelling cover or case with specific fitment for all users of the Abbott FreeStyle Libre 2 / 3  <b>Note:</b> System. <b>Sensor not included</b></p>
Safety-related Information
<p>Warning! This is not a toy. This product is not to be used by children under 3 years of age.          2.2. Disclaimer! The Libre Shield Armband 2 /3 is not a medical device accessory and doesn't specifically enable or disable the medical device Abbott FreeStyle Libre 3 System® to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device Abbott FreeStyle Libre 3 System® in terms of its/their intended purpose(s).</p>
Age range
<p>+3 years old</p>
Product picture



**Target markets**

Europe  
USA / Canada / Mexico

### 3. Compliance requirement and test reports

#### 3.1. Libre Shield Armband 3 – Black color

##### 3.1.1. Laboratory test results for the European market

<b>Test Requested</b>	
Azo Dyes - EU Regulation (EC) No. 1907/2006 of REACH Annex XVII Entry 43	<b>PASS</b>
Total Cadmium - EU Regulation (EC) No. 1907/2006 Annex XVII Entry 23	<b>PASS</b>
Phthalates –EU Regulation (EC) No. 1907/2006 Annex XVII Entry 51 & 52	<b>PASS</b>
Polycyclic Aromatic Hydrocarbons (PAHs) Content-Regulation (EC) No.1907/2006 Annex XVII Entry50, Point 5	<b>PASS</b>
Alkanes C10-13, chloro (Short Chain Chlorinated Paraffins) (SCCPs) content - Commission Regulation (EU) 2019/1021 on POPs	<b>PASS</b>
Restricted CMR Substances Content – Extractable heavy metals - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content – Polycyclic Aromatic Hydrocarbons (PAHs) - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content – Chlorinated Aromatic Hydrocarbons - REACH Annex XVII, Entry 72	<b>PASS</b>
Formaldehyde Content - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content – Phthalates - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content–solvent Residues - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content – Quinoline - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content – Dyes - REACH Annex XVII, Entry 72	<b>PASS</b>
Restricted CMR Substances Content – Arylamine - REACH Annex XVII, Entry 72	<b>PASS</b>
Polybromobiphenyls; Polybrominatedbiphenyls (PBB) - REACH Annex XVII, Entry 8	<b>PASS</b>
Tris (2,3 dibromopropyl) phosphate (TRIS) Content - REACH Annex XVII, Entry 4	<b>PASS</b>
Tris-azirdinyl phosphine oxide (TEPA) Content - REACH Annex XVII, Entry 7	<b>PASS</b>
Organostannic Compounds - REACH Annex XVII, Entry 20	<b>PASS</b>
Nonylphenol Ethoxylates (NPEOs) Content - REACH Annex XVII, Entry 46	<b>PASS</b>
Nonylphenol (NP) Content - REACH Annex XVII, Entry 46	<b>PASS</b>

Test Requested	CONCLUSION
Two hundred and forty-one (241) substances content in SVHC - ECHA's SVHC candidate on and before Jun. 27, 2024 of European Commission Regulation 1907/2006/EC concerning the REACH	LESS THAN 0.1% (w/w)



3.1.2. Laboratory test results for the U.S market

Total Lead - California Proposition 65	PASS
Total Cadmium - California Proposition 65	PASS
Phthalates - California Proposition 65	PASS
Lead (Pb) - US Consumer Products Safety Improvement Act(CPSIA) of 2008(H.R. 4040) title 1, section 101 for total lead content	PASS



### 3.2. Libre Shield Armband 2 – Black color

#### 3.2.1. Laboratory test results for the European market

Test Requested	
Azo Dyes - EU Regulation (EC) No. 1907/2006 of REACH Annex XVII Entry 43	PASS
Total Cadmium - EU Regulation (EC) No. 1907/2006 Annex XVII Entry 23	PASS
Phthalates –EU Regulation (EC) No. 1907/2006 Annex XVII Entry 51 & 52	PASS
Polycyclic Aromatic Hydrocarbons (PAHs) Content-Regulation (EC) No.1907/2006 Annex XVII Entry50, Point 5	PASS
Alkanes C10-13, chloro (Short Chain Chlorinated Paraffins) (SCCPs) content - Commission Regulation (EU) 2019/1021 on POPs	PASS
Restricted CMR Substances Content – Extractable heavy metals - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Polycyclic Aromatic Hydrocarbons (PAHs) - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Chlorinated Aromatic Hydrocarbons - REACH Annex XVII, Entry 72	PASS
Formaldehyde Content - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Phthalates - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content–solvent Residues - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Quinoline - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Dyes - REACH Annex XVII, Entry 72	PASS

Restricted CMR Substances Content – Arylamine - REACH Annex XVII, Entry 72	PASS
Polybromobiphenyls; Polybrominatedbiphenyls (PBB) - REACH Annex XVII, Entry 8	PASS
Tris (2,3 dibromopropyl) phosphate (TRIS) Content - REACH Annex XVII, Entry 4	PASS
Tris-azirdinyl phosphine oxide (TEPA) Content - REACH Annex XVII, Entry 7	PASS
Organostannic Compounds - REACH Annex XVII, Entry 20	PASS
NP and NPEOs Content - REACH Annex XVII, Entry 46	PASS

Test Requested	CONCLUSION
Two hundred and forty-one (241) substances content in SVHC - ECHA's SVHC candidate on and before Jun. 27, 2024 of European Commission Regulation 1907/2006/EC concerning the REACH	LESS THAN 0.1% (w/w)



3.2.2. Laboratory test results for the US market

Total Lead - California Proposition 65	PASS
Total Cadmium - California Proposition 65	PASS
Phthalates - California Proposition 65	PASS
Lead (Pb) - US Consumer Products Safety Improvement Act(CPSIA) of 2008(H.R. 4040) title 1, section 101 for total lead content	PASS



### 3.3. Libre Shield Armband 2 – Aquarius color

#### 3.3.1. Laboratory test results for the European market

Test Requested	
Azo Dyes - EU Regulation (EC) No. 1907/2006 of REACH Annex XVII Entry 43	PASS
Total Cadmium - EU Regulation (EC) No. 1907/2006 Annex XVII Entry 23	PASS
Phthalates –EU Regulation (EC) No. 1907/2006 Annex XVII Entry 51 & 52	PASS
Polycyclic Aromatic Hydrocarbons (PAHs) Content-Regulation (EC) No.1907/2006 Annex XVII Entry50, Point 5	PASS
Alkanes C10-13, chloro (Short Chain Chlorinated Paraffins) (SCCPs) content - Commission Regulation (EU) 2019/1021 on POPs	PASS
Restricted CMR Substances Content – Extractable heavy metals - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Polycyclic Aromatic Hydrocarbons (PAHs) - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Chlorinated Aromatic Hydrocarbons - REACH Annex XVII, Entry 72	PASS
Formaldehyde Content - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Phthalates - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content–solvent Residues - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Quinoline - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Dyes - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Arylamine - REACH Annex XVII, Entry 72	PASS
Polybromobiphenyls; Polybrominatedbiphenyls (PBB) - REACH Annex XVII, Entry 8	PASS
Tris (2,3 dibromopropyl) phosphate (TRIS) Content - REACH Annex XVII, Entry 4	PASS
Tris-azirdinyl phosphine oxide (TEPA) Content - REACH Annex XVII, Entry 7	PASS
Organostannic Compounds - REACH Annex XVII, Entry 20	PASS
NP and NPEOs Content - REACH Annex XVII, Entry 46	PASS

Test Requested	CONCLUSION
Two hundred and forty-one (241) substances content in SVHC - ECHA's SVHC candidate on and before Jun. 27, 2024 of European Commission Regulation 1907/2006/EC concerning the REACH	LESS THAN 0.1% (w/w)



3.3.2. Laboratory test results for the US market

Total Lead - California Proposition 65	PASS
Total Cadmium - California Proposition 65	PASS
Phthalates - California Proposition 65	PASS
Lead (Pb) - US Consumer Products Safety Improvement Act(CPSIA) of 2008(H.R. 4040) title 1, section 101 for total lead content	PASS



### 3.4. Libre Shield Armband 2 – Purple color

#### 3.4.1. Laboratory test results for the European market

Test Requested	CONCLUSION
Azo Dyes - EU Regulation (EC) No. 1907/2006 of REACH Annex XVII Entry 43	PASS
Total Cadmium - EU Regulation (EC) No. 1907/2006 Annex XVII Entry 23	PASS
Phthalates –EU Regulation (EC) No. 1907/2006 Annex XVII Entry 51 & 52	PASS
Polycyclic Aromatic Hydrocarbons (PAHs) Content-Regulation (EC) No.1907/2006 Annex XVII Entry50, Point 5	PASS
Alkanes C10-13, chloro (Short Chain Chlorinated Paraffins) (SCCPs) content - Commission Regulation (EU) 2019/1021 on POPs	PASS
Restricted CMR Substances Content – Extractable heavy metals - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Polycyclic Aromatic Hydrocarbons (PAHs) - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Chlorinated Aromatic Hydrocarbons - REACH Annex XVII, Entry 72	PASS
Formaldehyde Content - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Phthalates - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content–solvent Residues - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Quinoline - REACH Annex XVII, Entry 72	PASS
Restricted CMR Substances Content – Dyes - REACH Annex XVII, Entry 72	PASS

Restricted CMR Substances Content – Arylamine - REACH Annex XVII, Entry 72	PASS
Polybromobiphenyls; Polybrominatedbiphenyls (PBB) - REACH Annex XVII, Entry 8	PASS
Tris (2,3 dibromopropyl) phosphate (TRIS) Content - REACH Annex XVII, Entry 4	PASS
Tris-azirdinyl phosphine oxide (TEPA) Content - REACH Annex XVII, Entry 7	PASS
Organostannic Compounds - REACH Annex XVII, Entry 20	PASS
NP and NPEOs Content - REACH Annex XVII, Entry 46	PASS

Test Requested	CONCLUSION
Two hundred and forty-one (241) substances content in SVHC - ECHA's SVHC candidate on and before Jun. 27, 2024 of European Commission Regulation 1907/2006/EC concerning the REACH	LESS THAN 0.1% (w/w)



3.4.2. Laboratory test results for the US market

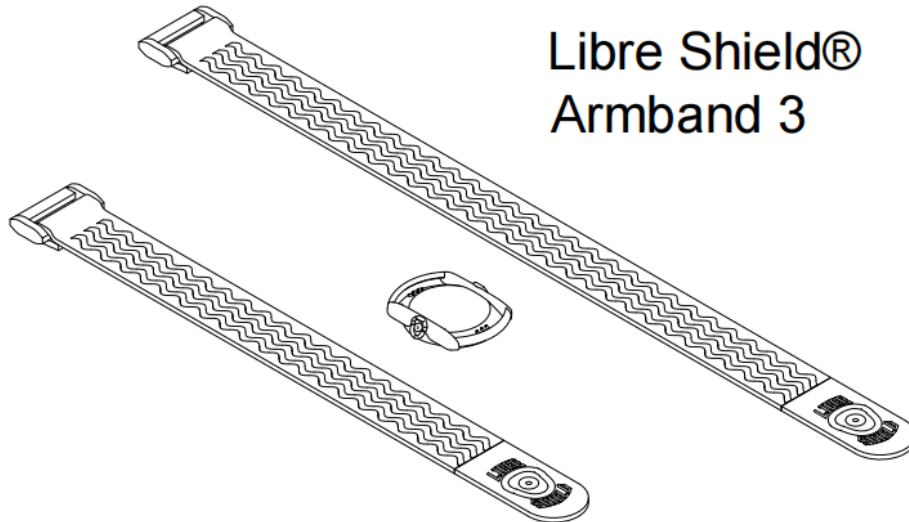
Total Lead - California Proposition 65	PASS
Total Cadmium - California Proposition 65	PASS
Phthalates - California Proposition 65	PASS
Lead (Pb) - US Consumer Products Safety Improvement Act(CPSIA) of 2008(H.R. 4040) title 1, section 101 for total lead content	PASS



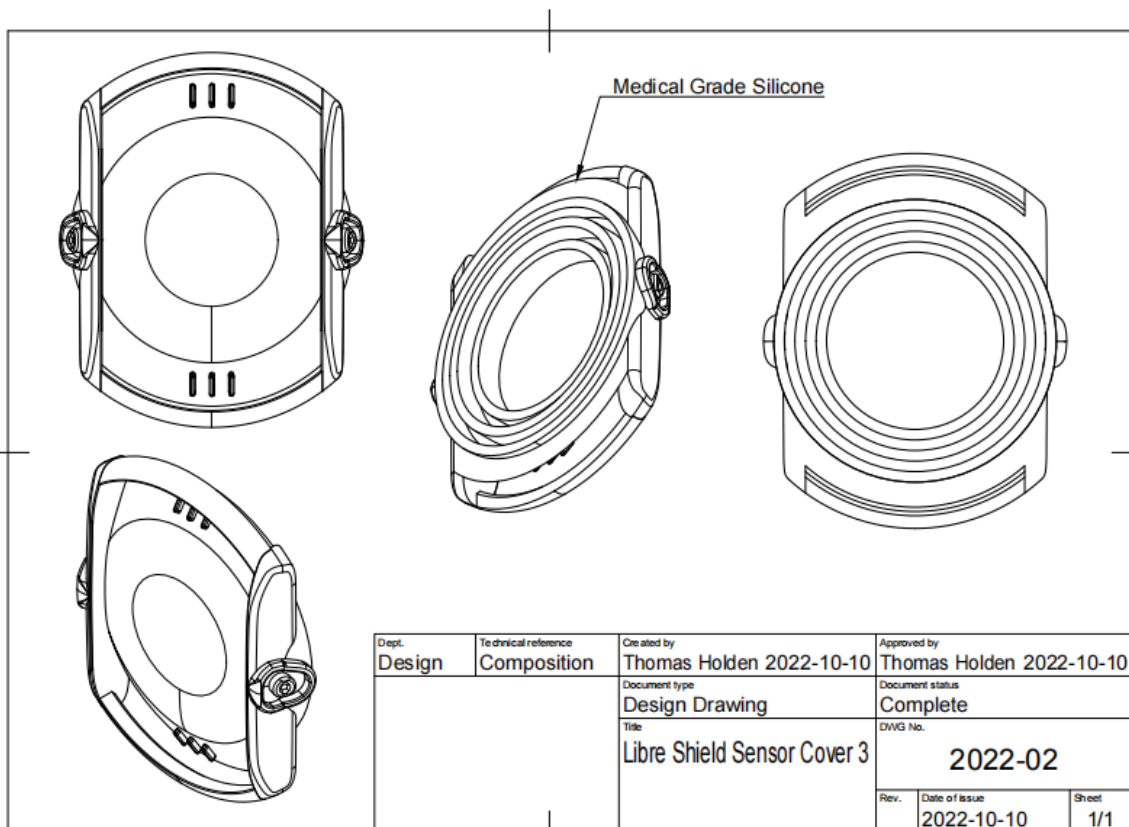
## 4. Technical specifications

### 4.1. Libre Shield Armband 3 – Black color

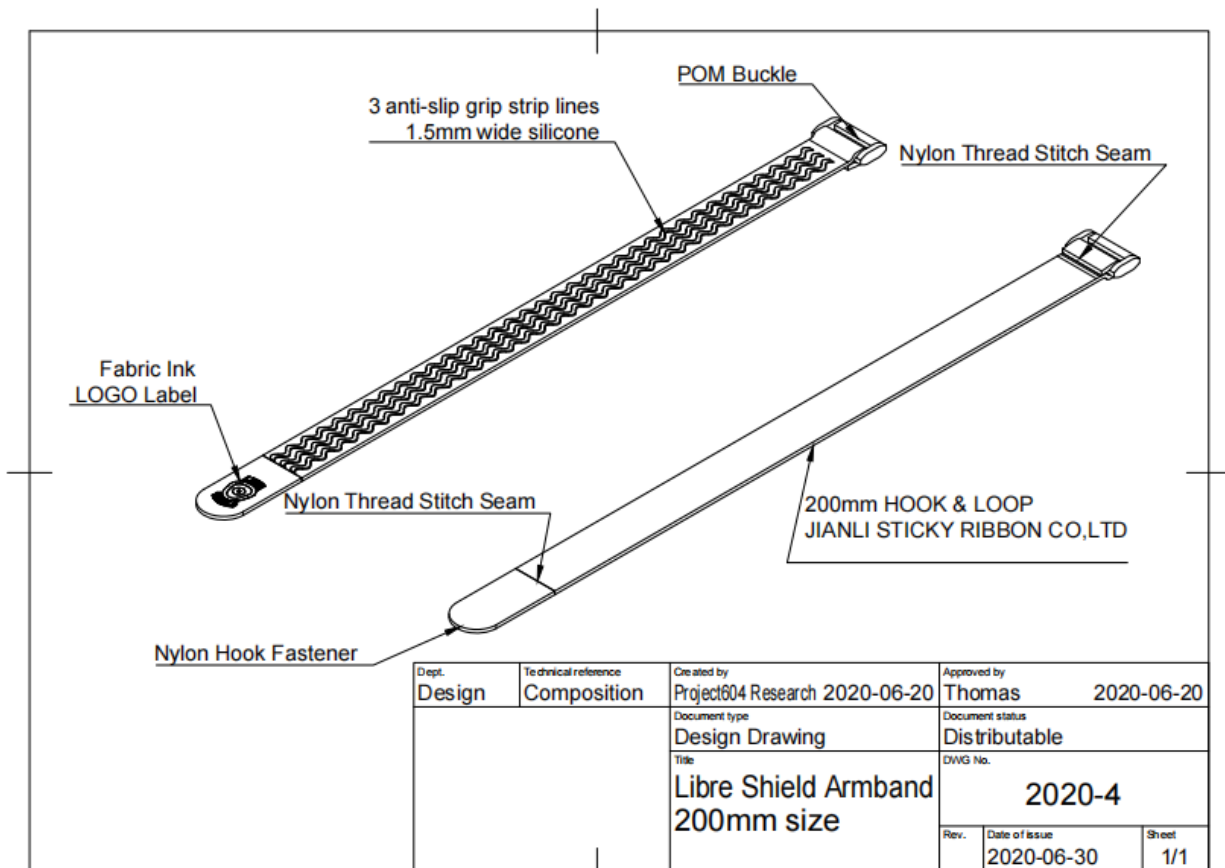
#### 4.1.1. Package - components: Drawing



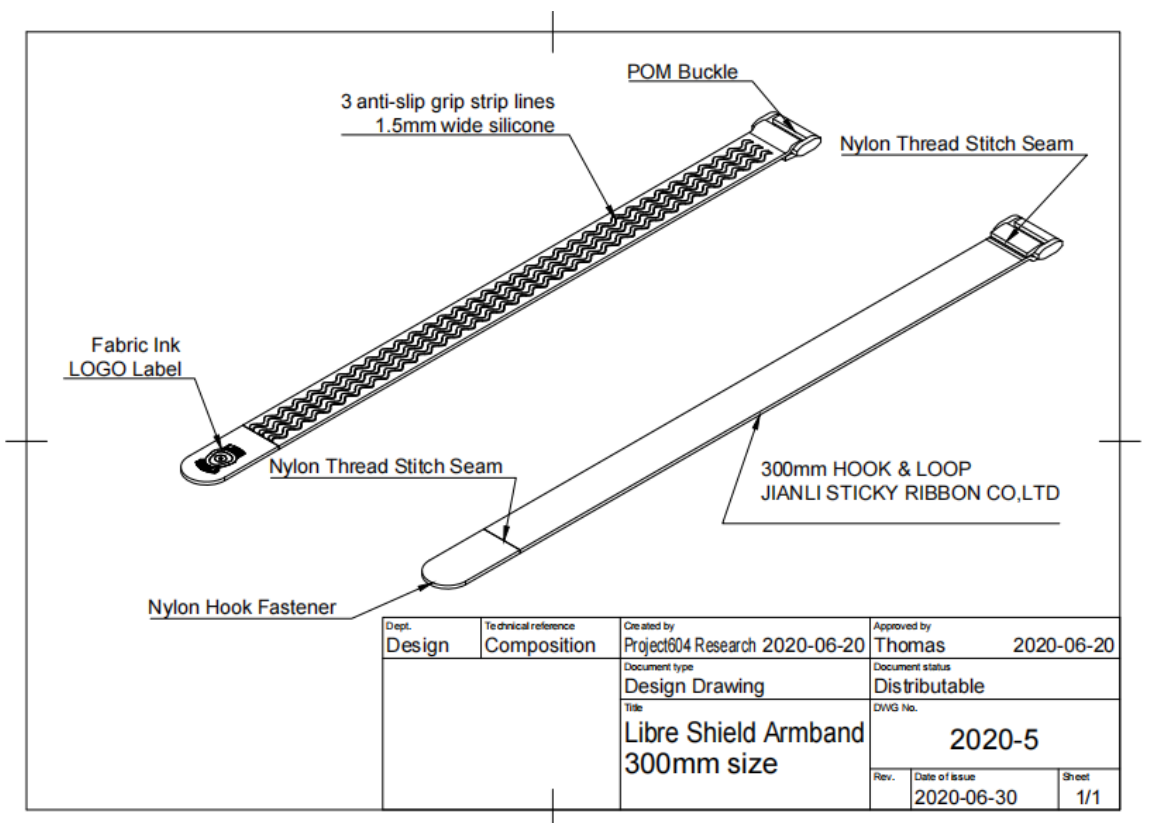
#### 4.1.2. Sensor cover case - composition: Drawing



4.1.3. Libre Shield 200mm Armband – Materials composition: Drawing

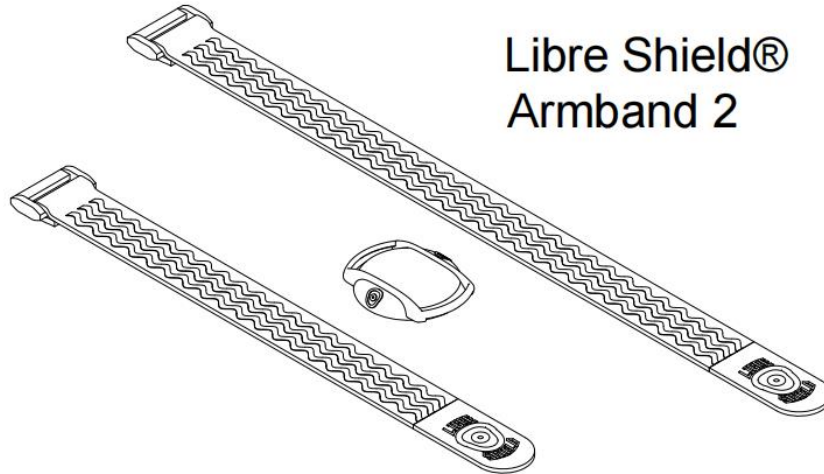


4.1.4. Libre Shield 300mm Armband – Materials composition: Drawing

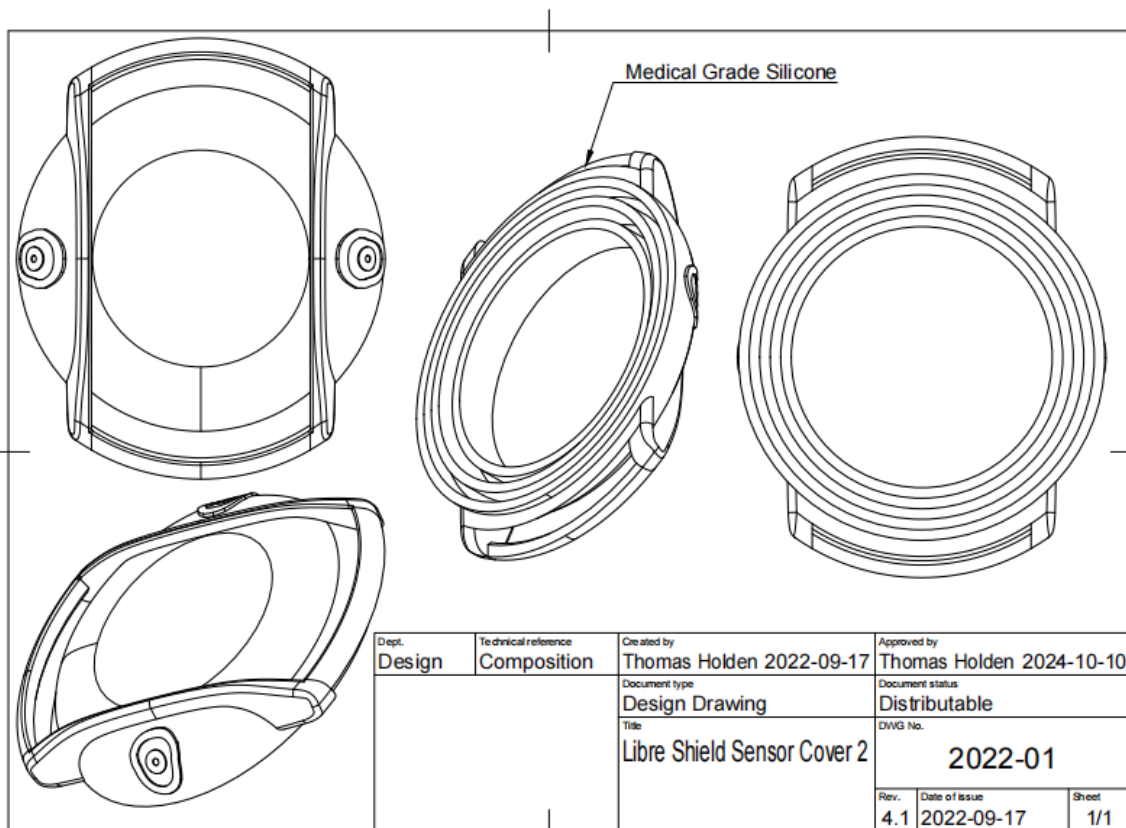


## 4.2. Libre Shield Armband 2 – Black color / Aquarius color / Purple

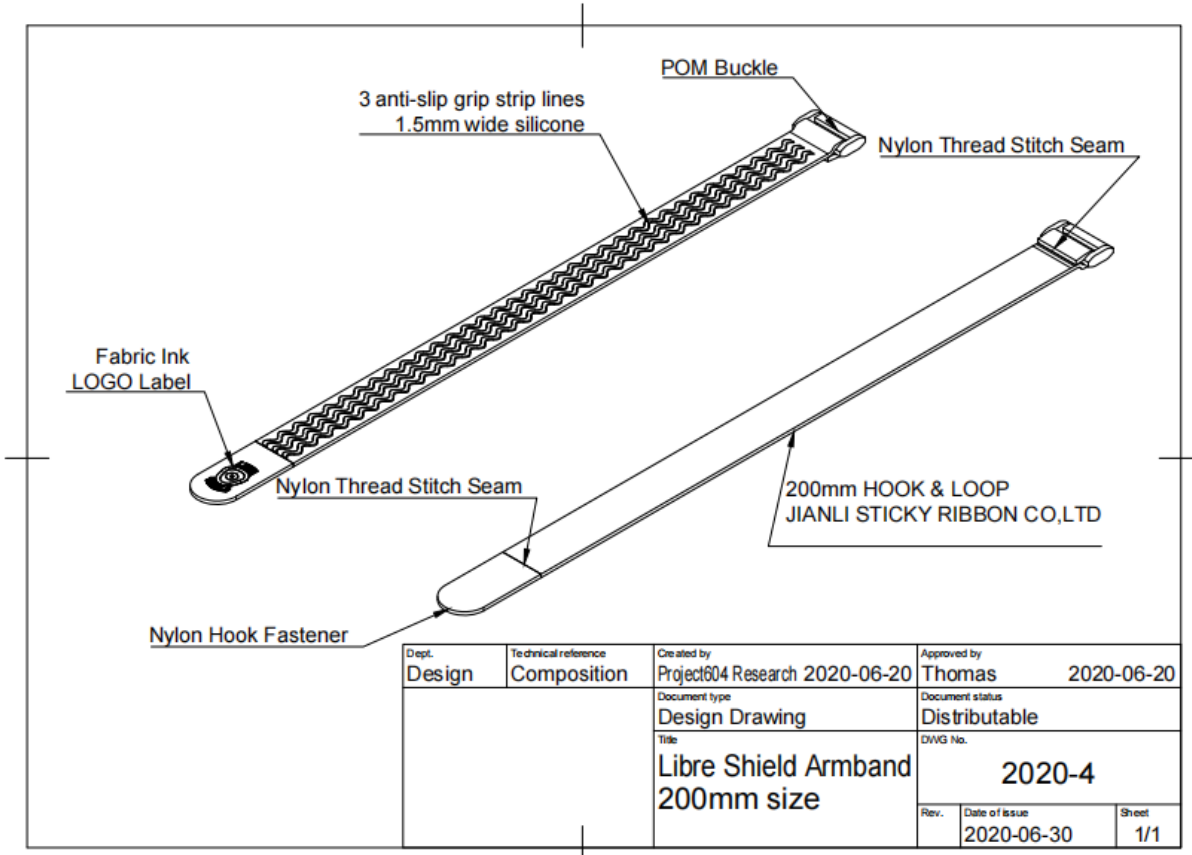
### 4.2.1. Package - components: Drawing



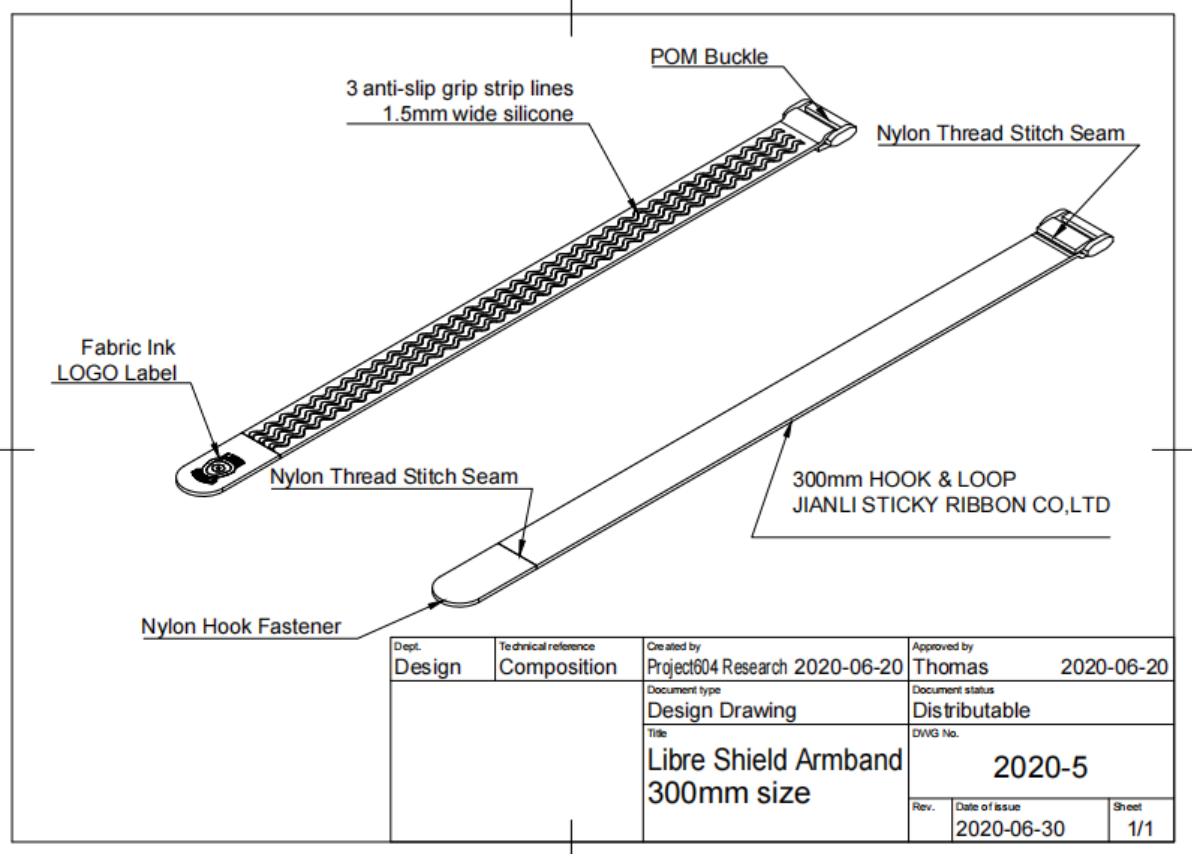
### 4.2.2. Sensor cover case - composition: Drawing



4.2.3. Libre Shield 200mm Armband – Materials composition: Drawing

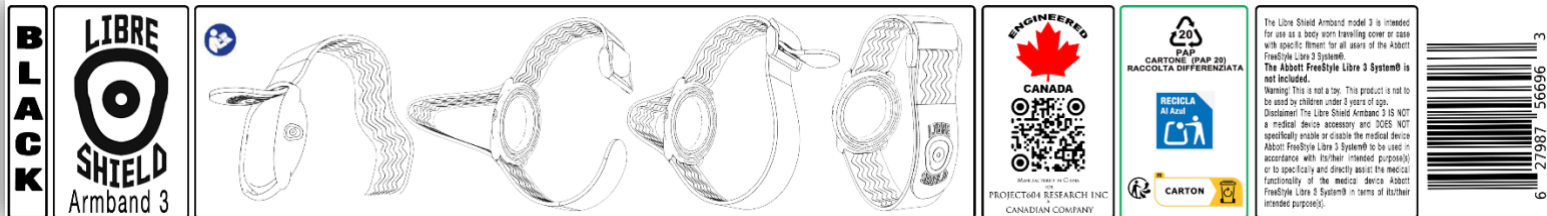


4.2.4. Libre Shield 300mm Armband – Materials composition: Drawing

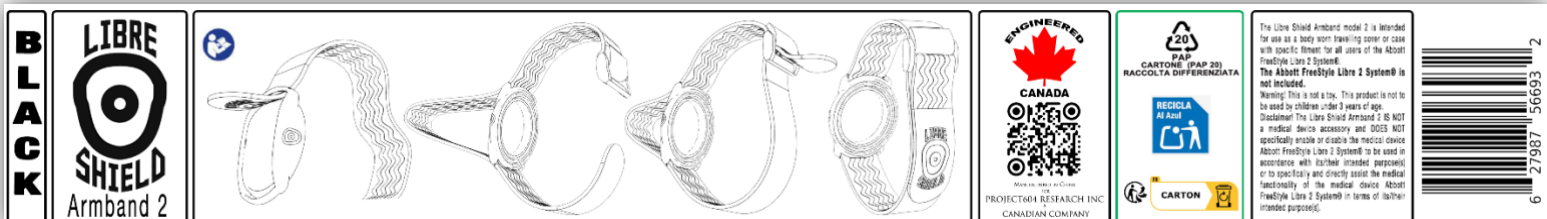


## 5. Labelling and Packaging

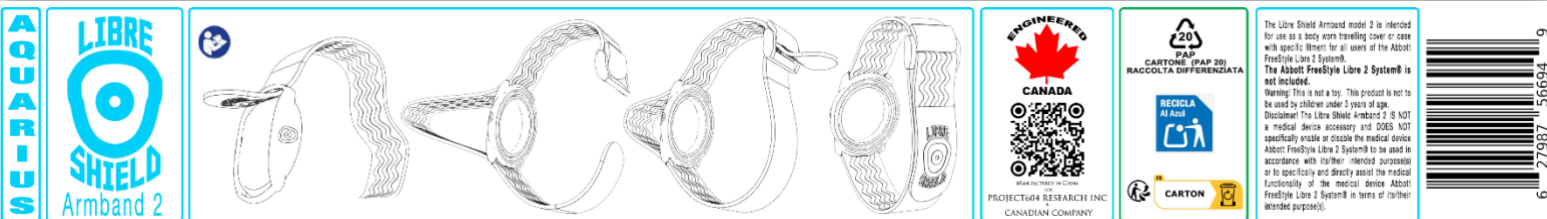
### 5.1. Libre Shield Armband 3 – Black color



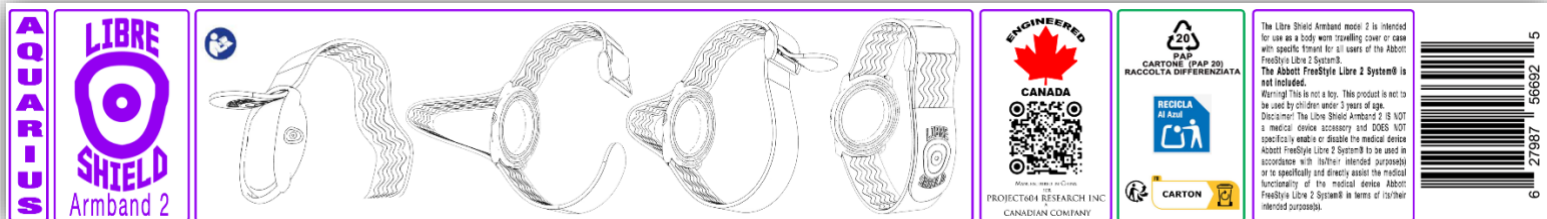
### 5.2. Libre Shield Armband 2 – Black color



### 5.3. Libre Shield Armband 2 – Aquarius color



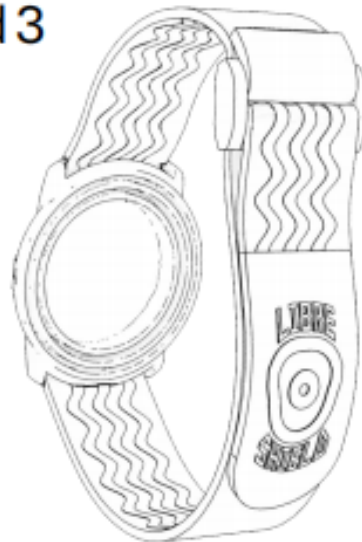
### 5.4. Libre Shield Armband 2 – Purple color



## 6. User instruction manual

### 6.1. Libre Shield Armband 3 – Black color

#### Instructions for Assembly and Use of the Libre Shield® Armband 3



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3. Identifier	2	Approved
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6. Use of Libre Shield® Armband 3	4	Approved
7. Maintenance of Libre Shield® Armband 3	4	Approved

## 1. Product Description

1.1. The Libre Shield Armband 3 is intended for use as a body worn travelling cover or case with specific fitment for all users of the *Abbott FreeStyle Libre 3 System*. **Sensor not included.**

## 2. Safety-related Information

2.1. Warning! This is not a toy. This product is not to be used by children under 3 years of age.

2.2. Disclaimer! The Libre Shield Armband 3 **IS NOT** a medical device accessory and **DOES NOT** specifically enable or disable the medical device *Abbott FreeStyle Libre 3 System*<sup>®</sup> to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device *Abbott FreeStyle Libre 3 System*<sup>®</sup> in terms of its/their intended purpose(s)

**The *Abbott FreeStyle Libre 3 System*<sup>®</sup> is not included.**

## 3. Identifier

### 3.1. Identification of information for use

3.1.1. Instructions for Assembly and Use of the Libre Shield Armband 3

3.1.2. Document ID: 2024LSA3001

3.1.3. Issued July 26, 2024

3.1.4. Rev 1.1, July 24, 2024

3.1.5. Language English

### 3.2. Identification of the product

3.2.1. Name: Libre Shield Armband 3

3.2.2. Product #: HW0005

3.2.3. Included Configurations: small, large, extra-large

3.2.4. Illustration of components



Libre Shield®  
Armband 3

### 3.3. Identification of the supplier

#### 3.3.1. Name and Address

Project604 Research Inc.  
4014 Brisbane Court,  
Abbotsford,  
British Columbia,  
Canada  
V4X 2S6

#### 3.3.2. Contact Details

Toll Free: +1 888 606 3057  
Phone: +1 604 245 6942  
email: support@project604research.com

### 4. Importance of retaining printed information for use



For safe and proper use,  
follow these instructions.  
Keep them for future reference.

### 5. Preparation for use

#### 5.1. Verify Package Components



## 5.2. Libre Shield Armband model 3 Assembly Instruction



## 6. Use of Libre Shield Armband 3



## 7. Maintenance of Libre Shield Armband 3

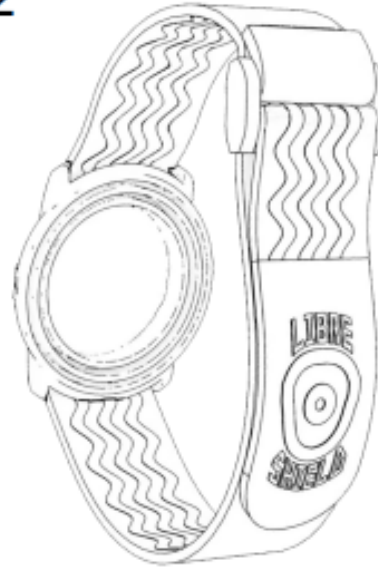
- a. Wash by hand with warm water and mild soap or detergent.
- b. Rinse clean.
- c. Air dry.

## 8. For More Information, Support, and Troubleshooting



6.2. Libre Shield Armband 2 – Black/Aquarius/Purple color

# Instructions for Assembly and Use of the Libre Shield® Armband 2



## Table of Contents

	Page	
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6. Use of Libre Shield® Armband 2	4	Approved
7. Maintenance of Libre Shield® Armband 2	4	Approved

## 1. Product Description

- 1.1. The Libre Shield Armband 2 is intended for use as a body worn travelling cover or case with specific fitment for all users of the *Abbott FreeStyle Libre 2 System*. **Sensor not included.**

## 2. Safety-related Information

- 2.1. Warning! This is not a toy. This product is not to be used by children under 3 years of age.
- 2.2. Disclaimer! The Libre Shield Armband 2 **IS NOT** a medical device accessory and **DOES NOT** specifically enable or disable the medical device *Abbott FreeStyle Libre 2 System*® to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device *Abbott FreeStyle Libre 2 System*® in terms of its/their intended purpose(s)  
**The *Abbott FreeStyle Libre 2 System*® is not included.**

## 3. Identifier

### 3.1. Identification of information for use

- 3.1.1. Instructions for Assembly and Use of the Libre Shield Armband 2
- 3.1.2. Document ID: 2024LSA2001
- 3.1.3. Issued July 26, 2024
- 3.1.4. Rev 1.1, July 24, 2024
- 3.1.5. Language English

### 3.2. Identification of the product

- 3.2.1. Name: Libre Shield Armband 2
- 3.2.2. Product #: HW0002
- 3.2.3. Included Configurations: small, large, extra-large
- 3.2.4. Illustration of components



### 3.3. Identification of the supplier

#### 3.3.1. Name and Address

Project604 Research Inc.  
4014 Brisbane Court,  
Abbotsford,  
British Columbia,  
Canada  
V4X 2S6

#### 3.3.2. Contact Details

Toll Free: +1 888 606 3057  
Phone:+1 604 245 6942  
email: support@project604research.com

### 4. Importance of retaining printed information for use



For safe and proper use,  
follow these instructions.  
Keep them for future reference.

### 5. Preparation for use

#### 5.1. Verify Package Components



Libre Shield®  
Armband 2

## 5.2. Libre Shield Armband model 2 Assembly Instruction



## 6. Use of Libre Shield Armband 2



## 7. Maintenance of Libre Shield Armband 2

- a. Wash by hand with warm water and mild soap or detergent.
- b. Rinse clean.
- c. Air dry.

## 8. For More Information, Support, and Troubleshooting



**Note: The risk assessment report is in a separate file.**

**END OF THE REPORT**