**Product Requirements Document**
***ActivFlow Sport:* Insulin Drug Delivery System**

# 1 Introduction

## 1.1 Overview

Diabetes refers to a group of chronic diseases that involve issues with the hormone insulin and result in elevated blood glucose (hyperglycemia). Though the disease can be managed, it is a lifelong health condition that affects the day-to-day activities of over 450 million people worldwide. Diabetes is a major contributor to heart, kidney, and vascular diseases in addition to strokes and vision loss due to the increased risk of hyperglycemia. If left untended or improperly treated, diabetes can even result in death.

For people without diabetes, the body naturally processes consumed calories into energy via insulin enabling glucose to move from the bloodstream into cells. If an individual has Type I diabetes, the insulin-signaling cells in their pancreas have been destroyed by autoimmunity; the body fails to produce insulin altogether. Individuals with Type II diabetes do produce insulin, but have developed a resistance to the action of the hormone on its receptor, requiring additional insulin to overcome cells' weak response. In both cases, insulin injections are critical to the regulation of blood glucose levels.

Maintaining a healthy lifestyle by monitoring blood glucose and taking regular insulin injections necessitates near-continuous individual attention. These injections add extra insulin to the bloodstream, overcoming the lack of produced insulin or overcoming the developed resistance against the hormone. Scheduled meals and snacks, precise dosage calculations, and planned exercise become a requisite part of any daily routine. Biomedical devices such as insulin pumps may serve to relieve this regulatory burden while performing their intended function. A standard insulin pump contains programmable electronics to monitor blood glucose levels and regulate the flow of insulin from an internal reservoir to a cannula that must be relocated by the user on a weekly basis.

Highly active individuals like athletes face extra challenges in managing diabetes while performing activities of daily life. Strenuous physical activity consumes energy produced in the body and can lead to low blood sugar (hypoglycemia), which in turn may cause poor balance, heart palpitations, and loss of consciousness. Athletes are thus forced to repeatedly break in the middle of games and practices to check their blood glucose levels and consume additional carbohydrates.

Competitive athletes with diabetes have a specific set of needs: treatment must continue during periods of intense physical activity. This means that the user must be able to move quickly without fear of dislodging the device or experiencing discomfort. Devices, like insulin pumps, that can be worn during periods of physical activity to monitor BG and perform basal insulin injections do not satisfy said user needs for agility, comfort, and safety. Since these requirements are not currently fulfilled, many competitive athletes opt to remove their devices and ignore diabetic treatment for the hours in which they are engaged in a game or match. This can be extremely dangerous for their health and wellbeing and can lead to a higher risk of hyperglycemia. For this reason, *ActivFlow Sport* will cater to the population of athletes with Type I diabetes by providing an accurate and safe dual-regulatory system to manage both high and low blood glucose levels. A three-hour worry-free window will ensure any athlete's safety while they take

break from monitoring diabetes to focus on their passion. To further ease user burden, the design allows the wearer to maintain their original injection site while they swap out a standard electronic pump for the *ActivFlow Sport* device.

## 1.2 Naming conventions

The use of the term "shall", when underlined indicates a requirement that is a "Must Have" and the use of the term "should", when underlined is a "Nice to Have" requirement.

Blood Glucose (BG): A measure of glucose molecules in the bloodstream in milligrams per deciliter.

Bolus: A high concentration of insulin taken in a single dose before meal times to keep blood glucose levels under control following a meal.

Basal: Small concentrations of insulin given in continuous doses to keep blood glucose levels at consistent levels during periods of fasting.

User: The individual that will use *ActivFlow Sport* to administer an injection. The user has been diagnosed with diabetes and prescribed insulin dosages by a medical professional.

Device: Medical insulin pump designed for use in active settings to regulate BG levels, and administer insulin via injection as needed.

Band: A shock-absorbing, reusable material that holds the device and allows it be worn snugly around the upper arm.

Pad: A shock-absorbing, reusable material that holds the device and allows it to be worn comfortably on the abdomen, upper thigh, or buttocks via adhesive strips.

Reservoir: Small storage chamber for insulin to be worn on the body as a part of the device.

*ActivFlow Sport*: A portable insulin pump designed for athletic use. Describes the set of the device and the band or pad.

*ActivFlow App:* A companion smartphone application to the *ActivFlow Sport* that allows the user to input individual settings, carbohydrate intake, information about periods of physical activity, and calculate resulting insulin dosages.

## 2 Reference Documents

Reference material used in the creation of this document:


- CDC'S Division of Diabetes Translation. (2017, April). Long-term Trends in Diabetes, United States Diabetes Surveillance System. Retrieved from https://www.cdc.gov/diabetes/data/
- American Diabetes Association. (2008, March). Statistics About Diabetes. Retrieved from http://www.diabetes.org/diabetes-basics/statistics/
- Diabetes Teaching Center at the University of California, San Francisco. (2018). Diabetes Education Online. Retrieved from https://dtc.ucsf.edu/
- National Institute of Health. (2015, February). PDB101: Molecule of the Month: Insulin Receptor. Retrieved from https://pdb101.rcsb.org/motm/182
- T1D Exchange. (2018, May). Diabetes Innovation Challenge. Retrieved from https://t1dexchange.org/pages/events/diabetes-innovation-challenge/
- T1D Exchange (2014, July). T1D Exchange Studies the State of T1D Care Internationally. Retrieved from https://t1dexchange.org/pages/t1d-exchange-studies-the-state-of-t1d-care-internationally/
- Dow Automotive (2018) Medical Silicone Adhesives. Retrieved from https://www.dow.com/en-us/transportation/solutions/medical-healthcare-solutions/medical-silicone-adhesives
- ANSI/AAMI/ISO 13485:2012 Medical Devices
- FDA Introduction to Medical Device Labeling
- FDA Regulation 21 CFR Part 11 - Electronic Records and Electronic Signatures
- ISO 14971 Medical Devices - Application of risk management to medical devices
- ISO 11040; ISO 11737-2 - Sterilization of Medical Devices
- ISO 10993 - Biocompatibility of Medical Devices
- Protection by Enclosure: IEC 60529
- Environmental Conditions: IEC 60601-1-11 Part 4.2
- Electromagnetic Compatibility: IEC 61000-4-4 ; IEC 61000-4-5
- Device Labeling: 21 CFR Part 801; 21 CFR Part 820; 21 CFR Part 830


## 3 General Requirements

| | |
|---|---|
| PPR3.1 | *ActivFlow Sport* shall measure blood glucose levels. |
| PPR3.2 | *ActivFlow Sport* shall have a companion smartphone application compatible with all major smartphone brands. |
| PPR3.3 | *ActivFlow Sport* shall recommend a dosage of glucose pills in conjunction with its haptic low blood glucose alerts via the companion smartphone application *ActivFlow App*. |
| PPR3.4 | *ActivFlow Sport* shall have enough storage for exactly two XX mg glucose pills in the band or pad. |
| PPR3.5 | The *ActivFlow Sport*'s companion app shall allow the user to connect wirelessly to the *ActivFlow Sport* device. |
| PPR3.6 | The user shall be able to program a bolus dosage of insulin from the app by inputting the number of carbohydrates they consumed. |
| PPR3.7 | *ActivFlow Sport* shall undergo a calibration procedure in which any data stored from the previously attached pump is passed via the *ActivFlow App* to the *ActivFlow Sport*, such that the *ActivFlow Sport* can seamlessly resume any programming from the previously attached pump. |
| PPR3.8 | *ActivFlow Sport* is designed to be worn for 6-8 hours, 3 of which shall require no additional programming (3 hour worry-free window). |
| PPR3.9 | *ActivFlow Sport* shall have a refillable insulin reservoir that would allow the user to wear the device for longer than the 6-8 hour recommended |

window if necessary.

PPR3.10 *ActivFlow Sport* shall be able to interface with existing infusion site connectors.

## 4 Communications

PPR4.1 *ActivFlow Sport* shall connect to *ActivFlow App* via Bluetooth Low-Energy profile.

PPR4.2 *ActivFlow Sport* shall support the *ActivFlow App* communication protocol (TBD).

PPR4.3 *ActivFlow Sport* shall not interfere with other RF devices.

PPR4.4 *ActivFlow Sport* shall transmit data in a encrypted format.

## 5 Shelf Life / Expiration Date

PPR5.1 *ActivFlow Sport* electronic pump shall have a Claimed Lifetime of 5 years.

PPR5.2 *ActivFlow Sport* bands shall have a Claimed Lifetime of 1 year.

PPR5.3 Insulin reservoirs shall have a shelf life equivalent to or greater than the shelf life of the approved medication (expected 30 days unrefrigerated or 3 months refrigerated).

PPR5.4 *ActivFlow Sport* reservoirs shall have expiration date labeling meeting the applicable regulatory requirements.

## 6 Injection

PPR6.1 *ActivFlow Sport* shall allow the user to visually inspect the medication for particulates and discoloration prior to refilling the device's built-in reservoir.

PPR6.2 *ActivFlow Sport*'s insulin reservoir shall have a capacity of 1 mL.This allows for storage of 100 units/reservoir, which exceeds the typical 2.5 units/hour basal insulin dose needed and 50-200 units/day required by a 50-100 kg person wearing *ActivFlow Sport* for a 3 hour window.

PPR6.3 *ActivFlow Sport* shall send an alert to the user when the insulin reservoir reaches XX mL via the companion smartphone app, and haptic alerts.

PPR6.4 *ActivFlow Sport* shall send alerts in increasing frequency to tell the user when the insulin reservoir nears empty in increments of 25% remaining, 15%, 10%, 5%, 2.5%, and 0%.

PPR6.5 *ActivFlow Sport* shall be able to deliver a basal dose within the range of 0.5-7 units per hour of insulin with 95% accuracy. This is a standard accuracy rate for insulin.

PPR6.6 The basal rate shall be a programmable value within the *ActivFlow Sport* smartphone app.

PPR6.7 *ActivFlow App* should allow adjusting bolus speeds between 0.5 and 18 units of insulin per minute with 97% accuracy. The standard bolus rate is 1.5 units per minute though severe hyperglycemia may require higher bolus speeds. Eighteen units per minute is the safest commercially acceptable rate for insulin pumps.

PPR6.8 *ActivFlow Sport* shall be compatible with existing injection sets manufactured by leading companies

PPR6.9 *ActivFlow Sport* shall have connectors to fit standard cannula lengths (6mm, 8mm, 10mm, 13mm).

PPR6.10 Tubing shall follow the shortest path from the injection site to the pump along the user's skin.

PPR6.11 The injection site shall be covered entirely by the band or pad.

PPR6.12 The removal and application of the *ActivFlow Sport* from an injection set shall not necessitate the removal of the injection set, thereby allowing other compatible pumps to be swapped easily with no new injection sites.

PPR6.13 The tubing of the injection set shall not be permanently set into *ActivFlow Sport*.

## 7 Mechanical Functional Requirements

PPR7.1 *ActivFlow Sport*'s internal computer shall be encased within a rigid plastic shell.

PPR7.2 The assembly (internal computer, insulin reservoir, needle, padding) shall be able to withstand 2000 Newtons of direct force caused by participation in contact sports (e.g., football tackle) with no injury to its components or the infusion site.

PPR7.3 The *ActivFlow Sport* bands shall utilize a strong adhesive (e.g. a platinum-catalyzed, filler-less, silicone elastomer) applied to the skin that secures the band to the body.

PPR7.4 The adhesive that secures the band to the body shall be able to withstand 10 Newtons of shear force.

PPR7.5 *ActivFlow Sport*'s adhesive patches for securing the device band or band to the user's skin shall be removable from the pad or band and from the user's skin with a required force no more than XX.

PPR7.6 The adhesive patches shall be disposable.

PPR7.7 *ActivFlow Sport's* arm and leg bands shall be able to conform to the circular shape of a cylindrical objects that the band's sizing advertises (e.g. a band advertising fitting limbs 30-36 cm in circumference must fit around cylindrical objects of the same dimension).

PPR7.8 *ActivFlow Sport's* internal components shall create a protrusion from the surface of the user's arm no greater than 1 cm.

PPR7.9 *ActivFlow Sport's* internal components should create a protrusion from the surface of the user's arm no greater than 1 cm.

PPR7.10 Glucose pill storage shall be able to withstand appropriate stresses to keep the pills protected.

## 8 Interface Requirements

PPR8.1 *ActivFlow Sport* shall be capable of interacting wirelessly with any major smartphone brand with the *ActivFlow App* installed.

PPR8.2 The device shall not have a user-interactive interface and shall rely solely on communication with external devices (i.e. a smartphone) for the sake of maintaining the necessary low profile of a sports-related device.

PPR8.3 If the device should malfunction or lose its connection to the paired smartphone, a unique vibrational and audible pattern shall be played by the device. At this point, the *ActivFlow Sport* may be swapped with a pump with a full interface.

PPR8.4 *ActivFlow Sport* shall not require an active connection to the smartphone app to be functional.

PPR8.5 *ActivFlow App* shall have programmable entries for the user's

height, weight, BMI, insulin requirements, and recommended glucose pill dosages.

PPR8.6 The *ActivFlow App* shall download all relevant user data to the device's computer when connected to the smartphone over bluetooth so that the device can continue autonomous operation in case of a lost connection.

PPR8.7 *ActivFlow App* shall send one notification per month as a reminder for the user to check that their medical information is up to date.

PPR8.8 *ActivFlow Sport*'s computer shall check for new available data each time it reestablishes a connection with the smartphone.

PPR8.9 The *ActivFlow App* shall check for new available data each time it reestablishes a connection with the device.

PPR8.10 The user shall be able to program a bolus dosage from the *ActivFlow App* that will cause the *ActivFlow Sport* pump to begin delivering insulin within fifteen seconds of the user completing the programming procedure on the smartphone.

PPR8.11 *ActivFlow App* data shall be kept entirely confidential within HIPAA Regulations.

PPR8.12 *ActivFlow Sport* should be capable of storing up to four past program settings with expected activity, heart rate, and other information used in calculating the correct time to ingest a glucose pill.

## 9 Electrical

PPR9.1 The *ActivFlow Sport* shall be automatically turned on when tubing is inserted into the device, which serves as an indication that the device is in use.

PPR9.2 The *ActivFlow Sport* shall be automatically turned off when tubing is removed from the device, which serves as an indication that the device is no longer in use.

PPR9.3 At startup, *ActivFlow Sport* self-test and any initialization shall complete in under 30 seconds when starting with a fully charged battery.

PPR9.4 Electrical circuitry shall be included for non-interference RF communication with *ActivFlow App*.

## 10 Battery

PPR10.1 *ActivFlow Sport* shall run continuously for 2 weeks without a need to recharge the batteries.

PPR10.2 *ActivFlow Sport* shall track the present state of charge of the battery.

PPR10.3 *ActivFlow Sport* shall include an externally accessible tab for battery removal.

PPR10.4 *ActivFlow Sport* battery should be able to be removed/applied in under 1 minute.

PPR10.5 *ActivFlow Sport* shall have markings dictating the proper orientation and voltages of the battery.

PPR10.6 When fully charged, *ActivFlow Sport* should be able to deliver at least two injections, three weeks apart, without recharging.

PPR10.7 *ActivFlow Sport* shall use a 5V *ActivFlow Sport*-specific rechargeable battery.

PPR10.8 The battery shall be a disc single cell battery of diameter no larger than

2.5 cm.

PPR10.9 The battery shall be rechargeable.

PPR10.10 The battery shall reach 0% to full charge states in 6 hours or less.

PPR10.11 *ActivFlow Sport* shall be sold with an external battery charging device.

PPR10.12 *ActivFlow Sport* shall have an external symbol on the battery case to indicate location.

**11 Adapter**

PPR11.1 *ActivFlow Sport* shall include a UL and CE listed, IEC-60601 compliant, power adapter and battery charger.

PPR11.2 The *ActivFlow Sport* battery adapter shall accept nominal input voltages from 80 VAC to 240 VAC.

PPR11.3 *ActivFlow Sport* battery adapter shall function for input voltages from 70 VAC to 250 VAC.

PPR11.4 The *ActivFlow Sport* battery adapter labelling shall indicate the nominal output voltage and battery type to be used with.

PPR11.5 The *ActivFlow Sport* battery adapter labelling shall indicate the nominal input voltage.

**12 Embedded System**

PPR12.1 *ActivFlow Sport* shall include an embedded processor to run the *ActivFlow Sport* software.

PPR12.2 *ActivFlow Sport* shall include relevant RF circuitry for communication with the *ActivFlow App*.

**13 User Interaction: Visual Cues**

PPR13.1 *ActivFlow Sport*'s insulin reservoir shall include a viewing window no smaller than 0.5 $cm^2$ through which the insulin may be inspected by the user.

PPR13.2 *ActivFlow Sport* shall have no visible lights or otherwise illuminated components for the sake of discretion

**14 User Interaction: Auditory Cues**

PPR14.1 The *ActivFlow App* shall alert the user if any attention is needed using an original and auditorily engaging notification sound played on the user's smartphone.

PPR14.2 *ActivFlow Sport* should have distinguishable audio alerts played by a small speaker within the device that correspond to the tactile vibrations and accompanying smartphone notifications. Example notifications may include a rising trill to indicate rising blood glucose, a descending trill to indicate dropping blood glucose, a triple beep to indicate that glucose pills are recommended, and a rapid beep to indicate low battery levels.

PPR14.3 *ActivFlow Sport*'s audio alerts should be mutable using controls within the *ActivFlow App* in the case that the user chooses to rely only on the tactile feedback.

**15 User Interaction: Tactile**

PPR15.1 *ActivFlow Sport* shall produce unique and easily distinguishable vibration or haptic patterns corresponding to various alerts. These patterns may include a vibration that increases in frequency to indicate rising blood glucose, a vibration that decreases in frequency to indicate dropping

blood glucose, a triple tap to indicate that glucose pills are recommended, and a repeating five-tap pattern to indicate low battery levels.

PPR15.2 *ActivFlow Sport* should play a unique feedback pattern corresponding to a recommended glucose pill ingestion at 10 minutes, 5 minutes, 1 minute, and 0 minutes before glucose pills must be ingested.

PPR15.3 *ActivFlow Sport* shall haptically alert the user if the device has calculated that BG levels are on trend to drop below a preset threshold (52 mL/dL) within 15 minutes.

PPR15.4 *ActivFlow Sport* vibrations shall have a maximum intensity of XX cm/s, per ISO 5349.

## 16 Error States

PPR16.1 *ActivFlow Sport* shall enter an error state which prevents the user from reprogramming if the remaining battery capacity is less than TBD mA-hrs.

PPR16.2 *ActivFlow Sport* shall enter into a system fault error state when it detects that it cannot initialize the microprocessor.

PPR16.3 *ActivFlow Sport* shall be able to detect a recoverable error state.

PPR16.4 *ActivFlow Sport* shall be able to detect a non-recoverable error state.

PPR16.5 *ActivFlow Sport* shall be able to communicate error states to the user with the paired *ActivFlow App*.

## 17 Data Logging

PPR17.1 For each injection, DEVICE shall log the time, date, dosage, and any error data from the injection

PPR17.2 DEVICE shall log injection data to nonvolatile memory

PPR17.3 DEVICE shall include sufficient nonvolatile storage to hold TBD months' worth of injection data, or data from TBD injections, whichever is greater

PPR17.4 DEVICE shall support logic to pack or remove verbose logging if storage space starts to run out.

PPR17.5 DEVICE shall have a means of maintaining the current date and time.

## 18 Ergonomic / Industrial Design

PPR18.1 *ActivFlow Sport* shall comply with FDA and ISO requirements for human factors design in medical devices. [2], [3]

PPR18.2 The *ActivFlow Sport* shall be marketed alongside bands of varying length that allow the user to adjust the device's fit to his or her liking.

PPR18.3 The adhesive on the bands shall be strong enough to withstand the shear strength of tightly applying the band such that the cannula does not shear against or through the user's skin.

PPR18.4 The bands shall be able to be removed from the application site by applying a pulling force no greater than 10 Newtons.

PPR18.5 The band shall be 7 cm wide.

PPR18.6 The *ActivFlow Sport*'s armbands shall be sold in three different sizes: small, medium, and large.

PPR18.7 The *ActivFlow Sport*'s "small" armband shall conform to arm sizes within the range of 20-30 cm in circumference.

PPR18.8 The *ActivFlow Sport*'s "medium" armband shall conform to arm sizes within the range of 30-40 cm in circumference.

PPR18.9 The *ActivFlow Sport*'s "large" armband shall conform to arm sizes within the range of 40-50 cm in circumference.

PPR18.10 The *ActivFlow Sport*'s leg bands shall be sold in three different sizes: small, medium, and large in circumference.

PPR18.11 The *ActivFlow Sport*'s "small" leg band shall conform to arm sizes within the range of 45-60 cm in circumference.

PPR18.12 The *ActivFlow Sport*'s "medium" leg band shall conform to arm sizes within the range of 60-75 cm in circumference.

PPR18.13 The *ActivFlow Sport*'s "large" armband shall conform to arm sizes within the range of 75-90 cm in circumference.

PPR18.14 The band shall be designed to be worn securely around the bicep.

PPR18.15 The pad shall come in a standard 7 centimeter by 7 centimeter package.

PPR18.16 *ActivFlow Sport* shall weigh less than 1 kg, with the DEVICE held by either the BAND or PAD.

## 19 Materials

PPR19.1 DEVICE shall comply with WEEE Waste Electrical & Electronic Directive 2012/19/EU 2012

PPR19.2 DEVICE shall comply with RoHS Hazardous Substances Electronic Equipment Directive 2011/65/EU

PPR19.3 DEVICE shall comply with REACH Registration Evaluation Authorization Restriction of Chemicals 2006.

PPR19.4 *ActivFlow Sport*'s internal computer casing shall be encased within a rigid plastic shell made of polycarbonate (or comparably strong plastics), the assembly of which shall be able to withstand 2000 Newtons of direct force.

PPR19.5 The *ActivFlow Sport* band shall utilize a non-latex skin adhesive (e.g. a platinum-catalyzed, filler-less, silicone elastomer [add reference]) with a peel strength range of XXX - XXX, per ASTM D903.

## 20 Environmental

PPR20.1 *ActivFlow Sport* shall be dust-tight and resistant to water splash and jets, per IP65 Enclosures, IEC 60529

PPR20.2 DEVICE shall operate under normal use humidity conditions (15-93% RH), per IEC 60601-1-11 section 4.2; (25% - 75% RH)

PPR20.3 DEVICE shall operate under normal use temperature conditions (5 C to 40 C), per IEC 60601-1-11 section 4.2; (18 C - 28 C)

PPR20.4 DEVICE shall operate under normal use pressure conditions (700 - 1060 hPA), per IEC 60601-1-11 section 4.2.

PPR20.5 *ActivFlow Sport* shall meet drop test requirements as specified in IEC 60601-1.

## 21 Packaging

PPR21.1 *ActivFlow Sport* in its shipping package shall meet the ship test specified in ISTA-2A, ISTA-3A, and/or ASTM-D4169

PPR21.2 *ActivFlow Sport* packaging shall use existing packaging features from current competitive products, avoiding the introduction of new packaging features.

PPR21.3 *ActivFlow Sport* packaging shall require less than TBD Newtons of force to remove (ex. ISO 11040-4).

PPR21.4 The *ActivFlow Sport* packaging container shall not exceed a volume TBD, with no one dimension exceeding a length TBD.

## 22 Labeling

PPR22.1 *ActivFlow Sport* shall comply with FDA and EU requirements for medical device labeling[1].

PPR22.2 *ActivFlow Sport* labeling shall clearly incorporate information for use (IFU) as required by the FDA and EU regulations.

PPR22.3 *ActivFlow Sport* labeling shall include humidity tolerance levels (humidity range TBD based on testing).

PPR22.4 *ActivFlow Sport* labeling shall include temperature tolerance levels (temperature range TBD based on testing).

PPR22.5 *ActivFlow Sport* labeling shall include information on how users can report complaints if they experience issues with the device.

PPR22.6 *ActivFlow Sport* labeling shall be simple, visible, clear and easily understood by the user.

PPR22.7 *ActivFlow Sport* labeling shall be able to withstand defacement or wear and tear over the claimed lifetime, including recommended cleaning.

PPR22.8 *ActivFlow Sport* reservoir labeling shall be compliant with the FDA, EU and pharmaceutical required labeling of the medication primary package container.

PPR22.9 *ActivFlow Sport* labeling shall include contraindications that clearly explain why any individual should not use the device, if any.

PPR22.10 *ActivFlow Sport* labeling shall include clear warnings and precautions.

PPR22.11 *ActivFlow Sport* labeling shall use consistent terminology throughout the labeling.

PPR22.12 *ActivFlow Sport* labeling shall use pictures, symbols and other graphics to aid understanding of instructional steps and other labeling materials, as appropriate.

PPR22.13 *ActivFlow Sport* labeling shall include information concerning the proper return and disposal of the device and its accessories.

PPR22.14 *ActivFlow Sport* labeling shall include a list of troubleshooting instructions.

## 23 Product Volumes / Forecast

PPR23.1 *ActivFlow Sport* should be manufactured at volume (>5000 units per year)

## 24 Manufacturing

### 24.1 Quality Systems

24.1.1 FDA Title 21, Part 820 of the CFR - Quality System Regulation (QSR): 1996 prior to US release for production

24.2.3 ANSI/AAMI/ISO 13485:2012 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

### 24.2 Assembly Area

24.2.1 *ActivFlow Sport* Reservoirs - Designated manufacturing space inside a class TBD clean room, with gowning and PPD

24.2.2 *ActivFlow Sport* Device - Designated manufacturing environment with ESD protection for electronics and assembly

### 24.3 Applicable Standards

24.3.1. Manufacturing of device shall comply with applicable standards/requirements.

[1] 21 CFR Part 801: Title 21 - Food and Drugs Chapter I; Food and Drug Administration; Department of Health and Human Services; Subchapter H - Medical Devices; Part 801 - Labeling

Current Good Manufacturing Practices (cGMP): 21CFR820

**25 Installation / Service / Maintenance**

PPR25.1 *ActivFlow Sport* shall be prescribed by a doctor with both written and online instructions available.

PPR25.2 *ActivFlow Sport* shall have an online help page and a 24-hour active help hotline.

PPR25.3 The DEVICE battery shall be removable with commonly available screwdrivers.

PPR25.4 DEVICE shall not require scheduled maintenance that is more labor-intensive than replacing a standard wrist watch battery.

**26 Biocompatibility, Toxicity and Sterility**

PPR26.1 The *ActivFlow Sport* shall be biocompatible with any type of human insulin.

PPR26.2 Any cannulas accompanying the *ActivFlow Sport* shall arrive fully sterilized per ISO 11737-2.

PPR26.3 All outward-facing or potentially exposable materials used on the *ActivFlow Sport*, including the cannula, the band fabric, the shock-absorbing material, and any plastics, shall comply with ISO 10993.

PPR26.4 All user accessible surfaces shall be biocompatible per ISO 10993-10.

PPR26.5 Fluid path and user contact materials shall be compatible with the requirements of ISO 10993.

**27 Regulatory Pathway**

PPR27.1 The *ActivFlow* DEVICE shall meet FDA, EU, ISO standards for medical devices and mobile connectivity.

PPR27.2 *ActivFlow* regulatory pathways shall be 510(k) in the US under 21 CFR Section 880.5430 non- electrically powered fluid injector.

PPR27.3 *ActivFlow Sport* shall have a CE Mark for marketing in the EU. The handheld will be approved as a medical device under Medical Device Directive 2.4/1 Rev 9 June 2010 Rule 12 - Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body.

**28 Cost of Goods Sold (COGS)**

PPR28.1 *ActivFlow Sport* should be manufactured at volume (>5000 units per year) for < USD XXX per unit.

**PRD REVISION HISTORY**

| Revision | Effective Date | Nature of Change | Originator(s) |
|---|---|---|---|
| A | 21Sep2018 | Initial Release | Zachary Davenport, Ava Lakmazaheri, Emma Westerhoff |
| B | 25Sep2018 | Minor changes for clarity and additional | Zachary Davenport, Ava Lakmazaheri, |

| | | | |
|---|---|---|---|
| | | requirements | Emma Westerhoff |