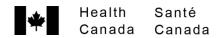
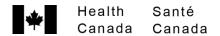


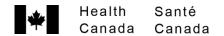
Application Information									
Application #: 313602 Licence #:		PRECISION BIOMONITORING INC.						oplication pe:	Device Class: 3
Manufacturer	N BIOMONITORII	NG INC.	IG INC.					Company ID: 152832	
DLSD Application Validation									
Risk Class & F	Rule:	Licence Type &		Special Substance			Applic	ation Form	at:
Class III by IVDD Rule 2(b)(i)		Test Kit	Amondm					_	
Fee Category: Reacon for Amendment:									
Reason for Amendment:							▼		
Bundle Information									
Bundle Ration	ale:		I Applications table included? Create/Modify Financial Bu					Info	
		'		-					
			Submission	on Completenes	ss				
MDR 32	Requirement					A D	N/A	A Notes/Comments	
32	Application Form	I							
32	Submission Pres	sentation (ToC	, Cover Let	tter, Exec Summ	ary)				
32(3a/4a)	Device Description								
32(3j/4p) 32(3g/4o)	QMS Certificate Labelling – 21(1a		-ISO 13485	5:2016					
02(0g/+0)	Labelling 21(18								
			DLSD Re	ecommendation	1				
	Incomple							_	
Rejection R	ationale:								
Notes/Comments: Despite multiple correspondence, I am yet to receive a complete IFU for the device. Do not have a complete intended use statement. Supporting data and evidence for safety/effectiveness appears to be for the general theory behind the test and does not specifically reference the proposed device (links in attachment of COMMUNICATION EXTERNAL [2020-04-07]). Their latest response (COMMUNICATION EXTERNAL [2020-04-14]) also refers to another party conducting research, but also suggests that Precision Biomonitoring Inc. has not conducted tests for their device as it states their device is a "lyophilized form of the tests".									
Steven McClelland Bureau of Licensing Services Medical Devices Directorate							Date: April 14, 2020		
Review Division – DLSD Communication									
Review Division Screener Action:									
Review Division Screener Response:									
							Date:		
Review Division	on Screener			_					



Medical Devices Directorate



Technica	<mark>l Screeni</mark> n	<mark>ig (Revi</mark>	ew Division)		
Proposed reviewer:			Estimated Review Time (days):	Review Complexity:	
		_			
Review Components	Review Required	Deficient	Comments		
Class III + IV					
General Application Organization					
Device Description					
Marketing History					
Standards & Conformity Declaration					
Analytical Performance					
Physical & Chemical Bench Testing					
Electrical & Radiation Safety					
Software Validation & Verification					
Biocompatibility & Pyrogenicity					
Sterilization, Packaging, &Shelf Life					
Animal Testing					
Stability					
Product Stability (Shelf Life)					
Usability					
Clinical Studies					
Bibliography					
Near patient IVDD					
Labelling					
	Cla	ss IV			
Risk Assessment					
Quality Plan					
Biological Safety					
Manufacturing Process					
Process Validation					
Note to the Reviewer (e.g. predicate, reference SBD?	nce, cautio	ons, direc	ctions)	Review incl.	
Recommendation					
				Ţ	
]	_				
Bundle Update/Modification – To DLS manage	er				
Rejection Rationale:					
Technical Screening Deficiencies:					
1.					





DLSD D	eficiencies	
Over Paid Fee Deficiency		
Please provide a completed Instructions for U You may review to Item 7 of the <u>Guidance</u> New Medical Device Licence for information Output Device for information Output Devi	Document -	- How to Complete the Application fo
Certificate Screening Checklist:		
☐ MDSAP ☐ Certificate Previous	ly Validated	
Cert # (new):	Cert Revisions /	/ Comments (If Applicable):
Cert. # (old):	-	
Replacing Existing Cert on File (Y/N):	_	
Criteria	Conforms	Comments/info for MDS
First (most prominent) and full name on cert. matches application/licence, and label.		·
Address on cert. matches application, licence, and label.		
Standard is (CAN/CSA) ISO 13485:2003 or 2016.		
Scope includes "manufacture" or "production". Scope includes "design" (fr. Conception) for Class III-IV.		
Scope is unambiguous and covers app. device. Scope does not contain specific product names / models / numbers or licence numbers. Reference to attachment is acceptable.		
Registrar is recognized.		
SCC logo and CMDCAS references are present.		
Effective date of registration. Field is identified as "Effective Date"		
Expiry date. Field is identified as "Expiry", "Expiry Date", or "Recertification Due Date"		
Validity period ≤ 3 years.		
Certificate contains Unique Certificate Number.		
Name, title, and signature of certification authority.		
All pages of certificate are present.		
Criteria	conforms	Comments/info for MDS
Issued to full name of manufacturer as it appears		Commence, and to the
on application/licence and label.		



Issued to complete civic address matching

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

	application/licence and label.			
	Criteria are ISO 13485:2003 or 2016 and Medical			
	Devices Regulations – Part 1 – SOR 98/282			
	Scope activities limited to design, development,			
	manufacture, production, servicing, installation, or			
	distribution.			
	Activities include "manufacture" or "production"			
	Activities include "design" or "development and			
	development" for class III/IV devices.			
	Scope is unambiguous and covers app./lic. devices.			
	Does not contain product names/models/licence			
	numbers.			
	Auditing Organisation is Authorized or Recognized			
	Statement of Authorization or Recognition.			
	Field labelled "Effective Date"			
	Field labelled "Expiry Date"			
	Validity period ≤ 3 years			
	Unique identification code labelled "certificate			
	number" or "certification document number"	_	☐ new ☐ revised	
	Name, title, and signature of certification authority			
	Pagination (page x or y) included on all pages . All			
	pages present.	_		
	Method to verify validity			
	, ,			
	700 44407 0 11: 77			
	ISO 13485 Quality Managemen	nt System C	Certificate Screening	
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