

AGREEMENT FOR USE OF NOVOPEN® SPECIFICATIONS

“Novo”	Novo Nordisk A/S, a company incorporated in Denmark with registered number 24256790 and with registered address Novo Allé, 2880 Bagsværd, Denmark.	
“Developer”	<i>Full name:</i>	
	<i>Country of incorporation:</i>	
	<i>Registration number:</i>	
	<i>Registered Address:</i>	
“Agreement”	This agreement for use of NovoPen Specifications.	
“Email Address” (for notices)	<i>Novo:</i>	digital-developer@novonordisk.com
	<i>Developer:</i>	
“Effective Date”	The date of last signature of the Parties.	

The parties will enter into the Agreement on the Effective Date.

Signed by for and on behalf of Novo Nordisk A/S Name: Title: Date:	Signed by for and on behalf of Developer Name: Title: Date:
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BACKGROUND:

(A) Novo is a global healthcare company specializing in the development of treatments for diabetes and other serious chronic conditions, and is the manufacturer of the NovoPen® 6 and NovoPen Echo® Plus (together referred to as the “NovoPen”), a medical device used to assist patients self-administer insulin and which is capable of connecting to certain digital mobile applications, software systems and devices to allow patients to view data stored on the NovoPen.

(B) Novo wishes to make the NovoPen as accessible as possible to patients and recognizes that third party mobile applications, software systems or other digital devices may help facilitate the use of the NovoPen.

(C) Novo is willing to share the Specifications (as defined below) with Developer so that Developer may connect Solutions (as defined below) to the NovoPen, subject to Developer’s compliance with the obligations set out in this Agreement.

AGREED TERMS:

1. DEFINITIONS

In this Agreement, the following terms shall have the following definitions:

1.1 “Affiliate” means any company or other entity which directly or indirectly controls, is controlled by or is under common control with a party, where ‘control’ means the ownership of more than 50% of the issued share capital or other equity interest or the legal power to direct or cause the direction of the general management and policies of such party, company or other entity.

1.2 “Applicable Law” means all laws, rules, regulations, codes of practice, or other requirements of regulatory authorities, as amended from time to time, including the Medical Devices Legislation and the Data Protection Legislation.

1.3 “Developer Content” means all text, information, data, software, executable code, images, audio or video material, in whatever medium or form, relevant for the purpose of using, developing or maintaining any Solution, and all information related to End-Users processed or stored by any Solution.

1.4 “Data Protection Legislation” means all applicable data protection legislation in force from time to time, including the General Data Protection Regulation (EU) 2016/679.

1.5 “End-User” means any user of the Solution.

1.6 “Intellectual Property” means all patents, utility models, rights to inventions, copyright and neighbouring and related rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all and other Intellectual Property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection that subsist or will subsist now or in the future in any part of the world.

1.7 “Medical Devices Legislation” means medical device legislation applicable to the Solution. For the avoidance of doubt, if the Solution is made available on the EU market, Medical Device Legislation shall include Directive 93/42/EEC and Regulation (EU) 2017/745.

1.8 “NovoPen Data” means all data, including any Personal Data, recorded by the NovoPen (e.g. dose, timestamp) or derived from Developer’s connection with the NovoPen.

1.9 “Personal Data” means any information relating to an identified or identifiable natural person.

1.10 “Specifications” means Novo’s specifications for the NovoPen and any other documentation or other materials, relating to the NovoPen made available by Novo to Developer for the purpose of connecting and integrating the Solutions to the NovoPen.

1.11 “Solution” means any mobile application, software system or other device developed by Developer which Developer intends to connect or integrate with the NovoPen.

1.12 “User Data” means any and all data, including any Personal Data and NovoPen Data, collected and processed by Developer through any Solution, or otherwise obtained in connection with Developer’s relationship with any End-User.

2. LICENSE TO SPECIFICATIONS

2.1 Novo will provide a copy of the Specifications and samples of the NovoPen to Developer following the Effective Date.

Subject to the terms of this Agreement (including clause 10.2), Novo hereby grants to Developer a worldwide, fully paid-up, non-exclusive, non-assignable, non-sub-licensable, license to use the Specifications, with effect from Developer’s receipt of such Specifications from Novo, solely as necessary or useful to connect and integrate the Solutions with the NovoPen.

2.2 Novo may change the NovoPen or Specifications from time-to-time at Novo’s discretion and Developer is solely responsible for procuring any updates and other amendments to the Solutions, and for maintaining the

functionality of the Solutions, as may be necessary to reflect any such changes to the NovoPen or Specifications.

2.3 Novo will, to the extent possible, notify Developer in advance of any changes to the NovoPen or the Specifications via email or the Novo Nordisk Developer Portal.

2.4 Developer will not under any circumstances use samples of the NovoPen for administering to humans or animals.

3. DEVELOPER OBLIGATIONS

3.1 Developer will comply with all Applicable Law in its performance of this Agreement.

3.2 Subject to and without limiting clause 3.1, Developer acknowledges and agrees that:

(a) for the purposes of the Medical Devices Legislation, Developer is the legal manufacturer of each Solution (to the extent such Solution is a medical device) and Novo is the legal manufacturer of the NovoPen;

(b) Developer will develop and market all Solutions in accordance with Applicable Law, including but not limited to only making the Solutions available in territories where the NovoPen is approved for use by the relevant regulatory authority, and is solely responsible for conducting pre-market testing and ongoing monitoring in respect of the Solutions. For the avoidance of doubt and irrespective of any provisions in this Agreement, Developer is expressly restricted from making the Solution available to individuals in the United States of America as well as making any statements directly or indirectly referring to NovoPen in any capacity or on any platform that addressing individuals residing in the United States of America;

(c) Developer is solely responsible for ensuring the safety and performance of the Solutions for their intended use and for any Developer Content, including content displayed to End-Users;

(d) Developer is solely responsible for verifying the suitability of the Specifications for the intended use of the Solutions;

(e) Novo is not responsible in any manner for the content or use of any Solution or Developer Content or for the accuracy of any data obtained by End-Users through any Solution;

(f) Developer may not use any Novo Intellectual Property except to the minimum extent necessary to indicate that a Solution can connect with the NovoPen, and provided only that such use of Novo Intellectual Property is limited to use on the Developer’s website, on mobile application stores and/or as a push notification via the Solution to End-Users as specified below; where necessary to explain the functionality of the Solution. Notwithstanding the foregoing, Developer may not imply (directly or indirectly) that any Solution is compatible with the NovoPen or that it has been assessed or endorsed by Novo in any way. For the avoidance of doubt, Novo will not object to Developer using the following statement “The [Solution] connects with NovoPen” and Developer will not object to Novo using the following statement “NovoPen connects with [the Solution]”. In respect of the push notification Novo will not object to Developer informing End-Users of the connectivity with the NovoPen using the following statement: “[Solution] now connects with the NovoPen in selected countries, please visit [Developer website] for more information”. Developer shall not make any public statement, written or oral, referring to Novo’s devices or drugs without Novo’s prior review and written approval. Further, Developer will include the following prominent disclaimer on all Solutions: “[Solution] has NOT been developed with, assessed by, or in any way endorsed by Novo Nordisk A/S and compatibility has NOT been assessed by Novo Nordisk A/S for use with the NovoPen® 6 or the NovoPen Echo® Plus. [Developer] is the manufacturer of the [Solution] and is solely responsible for ensuring the safety and performance of the [Solution] for its intended use. Novo Nordisk A/S is not responsible in any manner for the content or use of the [Solution] nor for the accuracy of any data obtained through use of the [Solution]”; and

(g) Developer will without undue delay notify Novo of all field safety corrective actions (including recall procedures), adverse incidents, events, reports or complaints (“Safety Information”) relating to any Solution or otherwise relevant to the NovoPen and the parties will consult on such issues. Developer will be responsible for taking any relevant actions with respect to any such Safety Information as may be required by Applicable Law in relation to any Solution, including, where necessary, for communicating such Safety Information to the applicable governmental and regulatory authorities. For the avoidance of doubt, Novo will be responsible for taking any relevant actions with respect to any Safety Information relating to the NovoPen. Developer will promptly comply with all reasonable requests of Novo regarding the handling and reporting of any Safety Information.

(h) Solely to comply with post-market surveillance requirements under Applicable Law, Novo will at least annually provide Developer with a survey regarding the performance of the NovoPen. Developer shall respond to such surveys within 14 (fourteen) business days of receipt.

(i) Developer will once annually during the Term provide Novo with an overview of total number of End-Users and breakdown per country.

4. END-USERS

4.1 Developer will process all User Data in accordance with Applicable Law and Developer will have its own end user license agreement and privacy policy applicable to all End-Users who connect to each Solution.

4.2 Developer shall not access, analyse or otherwise process NovoPen Data beyond what is strictly necessary for the Solution to function for the End-User.

4.3 Developer shall not share or make any NovoPen Data available to any third party without Novo's prior written approval. Irrespective hereof, Developer may make NovoPen Data available to data vendors who work on behalf of Developer, solely to the extent necessary for said data vendors to provide data hosting, transfer and storage services to Developer, and Developer shall prohibit said data vendors from i) using the NovoPen Data for its own benefit, or for the direct or indirect benefit of any other third party, and ii) enriching or combining the NovoPen Data with other data or taking any other actions that may result in it being reasonably likely for the data vendor to identify an End-User.

4.4 Irrespective of clause 4.3, Developer may upon request from End-User, export NovoPen Data for that End-User to the End-User(s) healthcare professional, caregivers and/or clinical investigators for non-commercial use and to the extent that export is for the purpose of the End-User receiving medical care.

4.5 Upon Novo's request, Developer shall negotiate with Novo in good faith an agreement to enable Novo to access User Data for the NovoPen users. Any such agreement will be subject to Developer obtaining and maintaining any and all permits, consents, licenses and any other authorizations required to share any such User Data with Novo. Unless and until Novo and Developer agree and enter into such agreement, Developer will not share any User Data with Novo.

5. NO FEES

5.1 The parties acknowledge and agree that no license fees or other payments will be due under this Agreement in exchange for the rights granted under this Agreement. The parties acknowledge and agree that this fee arrangement is made in consideration of the mutual obligations set out in this Agreement.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 Novo will own and retain all Intellectual Property rights in or relating to or arising out of or in connection with the NovoPen and the Specifications. Except as expressly set out in this Agreement, Developer will not acquire any right, title or interest in any Intellectual Property of Novo.

6.2 Developer will own and retain all Intellectual Property rights in or relating to or arising out of or in connection with any Solution. Except as expressly set out in this Agreement, Novo will not acquire any right, title or interest in any Intellectual Property of Developer.

6.3 Developer is not permitted to use any names, trade names, trademarks, logos, marketing materials or any other Intellectual Property of Novo within any Solution nor related products and services, or for the promotion thereof, except where expressly set out in this Agreement or agreed by Novo in writing in advance of any such use. To the extent any such use is permitted, Developer's use of any such Intellectual Property will: (i) not bring Novo into disrepute; and (ii) terminate immediately on termination of this Agreement. If Novo reasonably objects to any such use then Developer will immediately stop using the relevant materials in the manner specified by Novo.

6.4 Developer will not perform analysis or create any external materials (for example, but not limited to publications, promotional materials, clinical study results) comparing data from or derived from Developer's connection with the NovoPen to other insulin drugs, other insulin pens or other insulin devices or systems.

7. CONFIDENTIALITY

7.1 Developer undertakes that it will not disclose to any person any information disclosed to it by Novo or its Affiliates, or otherwise acquired by Developer, prior to or in the course of or otherwise in connection with this Agreement concerning the business, affairs, clients, customers, trade secrets, technical know-how, clients or suppliers of Novo and/or its Affiliates, including the Specifications and samples of the NovoPen ("**Confidential Information**"), except as expressly permitted by clause 7.2. Confidential Information does not include any information that is in or comes into the public domain (other than through breach of this Agreement or other wrongful act by Developer) or that was lawfully known to Developer prior to disclosure by Novo or its Affiliates or acquisition by Developer in the course of this Agreement.

7.2 Developer may disclose Confidential Information:

(a) to its employees or subcontractors strictly on a need to know basis for the purposes of carrying out Developer's obligations under this Agreement. Developer will ensure that its employees and/or subcontractors to whom it discloses any Confidential Information are aware of the confidential nature of the Confidential Information prior to disclosure and comply with this clause 7 and Developer shall be responsible to Novo for any act or omission of any such employee or subcontractor; and

(b) as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority, provided that, unless prohibited by law or regulation, it notifies Novo in advance prior to making any such disclosure.

7.2.2 Developer may not use any Confidential Information for any purpose other than to exercise the limited right granted to it under clause 2.

7.3 All Confidential Information, including all documents and materials, and copies or extracts thereof, containing, reflecting, incorporating

or based on the Confidential Information, will be and remain the property of Novo.

8. WARRANTIES AND DISCLAIMERS

8.1 Developer warrants, represents and undertakes to Novo that it:
(a) has the necessary power and authority to enter into this Agreement;
(b) will comply with all Applicable Laws in performance of this Agreement; and
(c) will perform its obligations under this Agreement with the highest level of skill and care.

9. LIMITATION OF LIABILITY

9.1 Nothing in these terms will limit or exclude Novo's liability for:
(a) death or personal injury caused by its negligence, or the negligence of its employees, agents or subcontractors;
(b) fraud or fraudulent misrepresentation; or
(c) any other liability which cannot be limited or excluded by applicable law.

9.2 Subject to clause 9.1, Novo will not under any circumstances whatsoever be liable to Developer, whether in contract, tort (including negligence), breach of statutory duty, misrepresentation or otherwise, for any direct or indirect loss of profit, loss of business, depletion of goodwill and/or similar losses or loss or corruption of data or information, or pure economic loss, or for any other special, indirect or consequential loss, costs, damages, charges or expenses however arising under or in connection with this Agreement.

9.3 Except as expressly provided in this Agreement, there are no conditions, warranties or other terms binding on Novo with respect to actions contemplated by this Agreement. Developer acknowledges and agrees that to the maximum extent permitted by Applicable Law that the Specifications and samples of NovoPen are provided 'as is' and without any representations or warranties of any kind, express, implied or statutory, and Novo expressly disclaims any and all such warranties, including any warranty of merchantability, non-infringement, accuracy or fitness for a particular purpose. Novo will not under any circumstances whatsoever be liable for Developer's use of the NovoPen or any Solution nor for any Developer Content.

9.4 Developer will indemnify Novo and its Affiliates and its and their officers and employees from any claim, loss, liability or expense (including legal costs) in connection with any breach by Developer of this Agreement or Developer's use of any Solution, including in conjunction with the NovoPen.

10. TERM AND TERMINATION

10.1 This Agreement will come into force on the Effective Date and will remain in force until terminated by either party in accordance with clause 10.2 (the "**Term**").

10.2 Without affecting any other right or remedy available to it:

(a) Novo may at any time cease use of Specifications and/or suspend Developer's access to the Specifications; and
(b) either party may terminate this Agreement with immediate effect by giving written notice to the other party.

10.3 On termination of this Agreement for any reason:

(a) Developer will promptly destroy or delete the Specifications and any other materials (including any Confidential Information) in Developer's possession or control, and shall certify to Novo in writing its compliance with this clause 10.3(a)
(b) the accrued rights, remedies, obligations and liabilities of the parties as at expiry or termination will be unaffected, including the right to claim damages in respect of any breach of this Agreement which existed at or before the date of termination or expiry; and
(c) clauses 3, 4, 6, 7, 9 and 10.3, will survive termination and continue in full force and effect.

11. NOTICES

11.1 Notices under this Agreement must be sent *via* email to the other party's Email Address indicated in the Coversheet to this Agreement, which will be deemed received at the time of transmission, or if this time fall outside of Business Hours in the place of receipt, when Business Hours resume. "**Business Hours**" means 9.00 am to 5.00 pm Monday to Friday on a day that is not a public holiday in the place of receipt.

12. ASSIGNMENT

12.1 Developer may not assign or transfer any of its rights or obligations under this Agreement in whole or in part without the prior written consent of Novo.

13. ENTIRE AGREEMENT

13.1 This Agreement supersedes all previous conditions understandings, commitments, agreements or representations (other than fraudulent misrepresentations) whatsoever whether oral or written relating to the subject matter hereof and constitutes the entire agreement between the parties relating to the subject matter hereof. Each party acknowledges that in entering into this Agreement it does not rely on, and will have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement. Each party agrees that it will have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement in this Agreement.

14. WAIVER

14.1 No waiver of any term or condition of this Agreement will be effective unless made in writing and signed by the party against which enforcement of the waiver is sought. The waiver of any breach of any term or condition of this Agreement will not be construed as a waiver of any subsequent breach of a term or condition of the same or a different nature.

15. SEVERABILITY

15.1 The invalidity, illegality or unenforceability of any of the provisions of this Agreement will not affect the validity, legality and enforceability of the remaining provisions of this Agreement.

16. NO PARTNERSHIP

16.1 Nothing in this Agreement will constitute or be construed as constituting or establishing any partnership or joint venture between the parties for any purpose whatsoever.

17. GOVERNING LAW AND JURISDICTION

17.1 This Agreement, and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), will be governed by, and construed in accordance with the laws of Denmark.

17.2 Each party irrevocably agrees that the courts of Denmark will have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).