	Number document: **F-8.2-1/11A**	Rev. no: 5
	Document title: **BIOLOGICAL ANALYSES LABORATORY**	**Date of issue: 08.01.2024**
	ORDER NO.**:	**Valid from: 08.01.2024**
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*Mark the correct one   **To be completed by JCI

TO BE COMPLETED BY THE CUSTOMER

ORDER FOR:

QUOTE NO.: ....   AGREEMENT NO: ....   PRICE LIST POSITION

A. Customer Information	B. Contact person
Name: .... Adress: .... NIP (Tax ID):	Full name: .... Position: .... Phone no.: .... E-mail: ....
C. Description of the analysis ordered*	**D. Research method***

Biocompability testing:
   quantitative cytotoxicity - *in vitro*
   test for irritation - *in vitro*
 	
Cellular test
   cytotoxicity test
   IC50 determination
   kinetic studies on cell growth
   growth factor secretion test
 	
   other:
 	
Tests on reconstructed human tissues
   skin irritation test
   skin corrosion test
   the assessment of skin permeation of molecules
   eye irritation test
 	
   other:
	Method PN-EN ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: *In vitro* cytotoxicity tests
	
	Method PN-EN ISO 10993-23:2021-08, Evaluation of biological medical devices - Part 23: Irritation tests
	
	Method according to OECD guideline 431, *In Vitro* Skin Corrosion: Reconstructed Human Epidermis Test Method
	
	Method according to OECD guideline 439, *In Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method
	
	Method in accordance with OECD Guideline 492, Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage
	
	Other:

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E. Details of the sample	F. Sample category*
name of the sample: .... LOT no.: .... form of the sample: .... sample size (g/l/cm²): .... no. of samples:	medicinal product medical device dietary supplement non-categorized sample cosmetic raw material other:
G. Information about sample collection*	**H. Other***

collection and transport by the Customer
collection and transport by JCI
sample collection as per (procedure):
	the sample must be returned to the Customer
	after the tests the sample must be removed
	hazardous sample
	the required storage temperature:
	   2°C-8°C
	   -20°C
	   -80°C
	   15°C÷25°C

I. Test results and declaration of conformity*

Presentation of the test result	without specifying the measurement uncertainty	Including measurement uncertainty
Declaration of compliance of the result with the requirement	YES	NO
	The declaration of compliance will be presented in accordance with the document ILAC-G8:09/2019 after prior agreement of the decision-making principle with the client or according to another principle proposed by the client.	

The laboratory undertakes to maintain the confidentiality of any information obtained or generated during the performance of laboratory activities.

The laboratory analyzed the risks associated with the implementation of the commissioned tests.

The Client or other interested parties may file a complaint regarding the execution of the order and/or the test results in accordance with the procedure "Proceesing with complaints" SOP-10.2-1. The procedure is available for inspection at the headquarters of the Laboratory.

J. Analysis report*

to be sent to the Customer's e-mail address: ....

hard copy to be sent by post[1]
1- shipment at the cost of the Customer

Mark as appropriate
The client has the right to monitor the performance of the laboratory related to the work performed. Cooperation may include providing appropriate access to relevant areas of the laboratory to observe specific activities of laboratory activities performed for the client

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INFORMATION

According to Art. 13 of the regulation of the European Parliament and Council (EU) 2016/679 of 27 April 2016 on protection of physical persons in connection to processing of personal data and on free flow of such data, and on repeal of Directive 95/46/CE (general data protection regulation, further: GDPR), please be informed that your personal data is administered by Jagiellońskie Centrum Innowacji sp. z o.o. (further: JCI) (Data Administrator), address: ul. Bobrzyńskiego 14 (post code: 30-348 Kraków), entered to the National Court Register kept by the Regional Court for Kraków - Śródmieście in Kraków, XI Economy Department of the National Court Register, under number KRS 0000212725, with NIP (tax ID) 676 226-66-85 and REGON no. 356845374, with company capital of 11,667,900.00 PLN.

The Administrator designated the Personal Data Protection Officer. You can contact the Personal Data Protection Officer electronically at iodo@jci.pl or in a written form at the address of Data Administrator.

Your personal information will be processed to perform analysis of the submitted samples and to establish contact in order to properly perform the research.

Your personal data is processed based by legally justified JCI interest, i.e. keeping in touch, correspondence, Archiving, protection of economical, legal or financial interest of JCI, as well as pursuing claims. Your personal data will be processed not longer than required for the above-mentioned aims or until the end of claim limitation period.

Providing your personal information is strictly voluntary, however it is necessary for the analysis/research to be performed. JCI can share your personal data with third parties (recipients) that perform hosting or legal services for JCI, as well as with public administration authorities. Your personal data will not be sent to a third country/international organization.

You have a right to access your data, to request corrections or deletion if it is not in contrast to the realization of the aim of their processing (the so-called right to be forgotten), to request limiting processing or transferring of your data as well as right to object against processing. Moreover, you have a right to file a claim to supervising authority in case of discovering that the data is processed not according to GDPR.

You can withdraw your consent at any time, using the form or JCI contact information provided above.
I hereby confirm that I have read and acknowledged the content of the information above and the privacy policy, and I confirm that I provide my personal data.

....	....	....
Date	*Full name of the authorized person*	*Signature of the authorized person*

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TO BE COMPLETED BY JCI**	
K. The sample was accepted for analysis by	Full name:.. Date: ....

L. Evaluation of the accepted samples	Packaging condition:
	    not questionable/ not damaged
	    questionable/ damaged
	
	Sample condition:
	    sample suitable for testing/qualifies for analysis
	    sample not suitable for testing / does not qualify for analysis
	    comments about the condition of the samples:

M. Additional information from the Customer after the order was provided to the person directly responsible for the analyses	
N. Deviation card's number	
O. Completed by	Full name:.. Date: .... Signature: ....