PRIVACY INFORMATION NOTICE AND CONSENT FORM

Dear Patient/Donor,

The information below explains how your personal data will be processed in the context of the research project for which you are providing your samples to the hospital **Specialized Hospital for Active Treatment of Oncological Diseases – Sofia District, LLC 67 Gen. Stoletov Blvd., Bulgaria,** as described in more detail below ("**Project**"). At the end of the form, we will ask you to confer your consent(s) for the processing of your personal data. Providing your consent is entirely voluntary. If you are undergoing medical treatment, refusal to participate will have no impact on your care. However, please note that processing your data is essential for the purposes of the Project.

The Project

The Project aims at improving a system of analysis, called CellSearch ™, property of Menarini Silicon Biosystems Spa a company based in Italy ("**MSB**"), whose purpose is to enable the isolation, characterization and counting of the tumor cells contained in a blood sample. It is in fact demonstrated that the concentration of circulating tumor cells has a prognostic value in some types of tumor diseases. The future versions of CellSearch ™, which the Project aims at developing, will have enhanced features and functionalities compared to the current version. Some of such functionalities will be certified as an "in vitro diagnostic device" ("IVDD"), per Regulation (EU) 2017/746 ("IVDD Regulation"), i.e. they will be suitable for usage in medical practice; some of the functionalities will initially be developed for "research use only" ("RUO"), i.e. suitable only for research activities, but may become certified as IVDD at a later stage.

The Project specifically focuses on samples containing multiple myeloma tumor cells, and has the following two endpoints:

i) developing a new instrument ("**Product**") able to enrich and stain circulating tumor cells, and prepare them for being counted.

In this part of the Project, the Italian company MASMEC Spa ("**MASMEC**") is in charge of developing, testing, and manufacturing this new Product, in the capacity as legal manufacturer. To this end, both MASMEC and MSB will process the samples and use the extracted data so that MASMEC can create the technical dossier required by the competent Authorities to authorize the sale of the Product and monitor its quality.

The Product will replace the current component of CellSearch ™ with the same function, and will be certified as IVDD;

ii) developing algorithms ("Algorithms") that use machine learning technology for image analysis, and in particular for the counting of circulating tumor cells contained in cancer patients' blood samples processed with CellSearch ™. Such Algorithms will support healthcare professionals with diagnosis or prognosis determination by introducing methods for tumor cell identification and counting that will be faster and easier than analysis performed by healthcare professionals manually. The Algorithms are currently developed to support healthcare professionals

in the context of medical research ("Research Use Only"); however, should the result be of sufficient quality, the Algorithms will also be certified as IVDD. The development data will become part of the technical dossier of the Algorithms, maintained by MSB, and will be used by MSB throughout the Algorithms' lifecycle to optimize their performance and to fix any technical malfunctioning (so-called "debugging").

For the sake of clarity, your data will not be used in the context of medical research concerning your health or to make diagnoses, prognoses or medical decisions about yourself, but only to develop the Product and Algorithms: once developed, these latter will be used for diagnosis/research on other patients. The data will also not become part of the Product or Algorithms themselves, and will not be commercialized, but just become part of the Product's and Algorithms' development dossiers, maintained by MASMEC and MSB, respectively.

In addition to samples of cancer patients, the Project also entails the use of samples by healthy donors, as controls, to ensure the new techniques only provide reliable data. This is the reason why healthy volunteers will also be asked to participate.

For more information and to access the Project, you may contact your healthcare professional or MASMEC which collaborates with MSB for this Project.

Your data will be processed in compliance with privacy laws, in particular with the GDPR.

Who processes your data

MSB (jointly with MASMEC) and the hospital where you have donated your sample shall act as independent data controllers of your personal data, i.e. each of them will carry out processing operations for different purposes (the hospital for treatment purposes -where applicable; MSB and MASMEC, for scientific research purposes consisting in developing the Product), for which they will respectively retain full responsibility.

Who are and how to contact the Joint Data Controllers

The joint data controllers, pursuant to Article 26 GDPR, are:

MSB at its business address: Menarini Silicon Biosystems, Via G. Di Vittorio 21 B/3, 40013, Castel Maggiore (BO), Italy. MSB's Data Protection Officer may be reached via email at dpo@menarini.com

MASMEC at its business address: MASMEC SpA, via Dei Gigli 21, Modugno (BO), Italy. Data Protection Officer may be reached via email at dpo@masmec.com

MASMEC, in its capacity as legal manufacturer of the Product, and MSB, in its capacity as legal manufacturer and owner of CellSearch ™, and as developer of the Algorithms, will process samples and use the extracted data for the Project. for the Project.

You may request the essential terms of the joint controllership arrangement by writing to MSB or MASMEC.

What data will be processed by the Joint Controllers

MSB and MASMEC will in no case have access to your identity, but only to a code, associated with your samples, that will identify you – only your hospital/laboratory will know your identity, and will care to replace your name and identifying information from your samples and the documents associated therewith before making them available to MSB and MASMEC.

MSB and MASMEC will process your biological samples and the data generated from their analysis, ensuring their protection - each for the part of its relevance - by implementing adequate organizational and technical security measures, as prescribed by the GDPR.

Other information processed by the Joint Controllers are your sample ID, date of sampling, tumor type, tumor stage, treatment (ongoing/past, including for example line of treatment, treatment regimen, time in respect to treatment, treatment response). Your samples will also be screened against HIV, HBV, HCV by your hospital/laboratory; if you test positive for one or more, you will not be eligible to participate in this Project and no information about you will be shared with MSB/MASMEC while Your hospital/laboratory will care to inform you of the results. If you test negative, MSB/MASMEC will receive your samples, as well as the information mentioned above, without any reference to your name/surname, but only to your analysis results and to a code, and will thus be unable to identify you.

For what purpose and on which "legal basis" your data will be processed

The Project aims at achieving the endpoints stated above.

The legal basis of the processing is your consent, pursuant to art. (6(1)(a) and 9(2)(a) of the GDPR, as well as the need to comply with the laws that ensure the quality and safety of medical devices (art. 6(1)(c) and 9(2)(i) GDPR). You may withdraw your consent at any time –in such case, your samples will be destroyed, and no more data about you will be collected. Data collected up to the time of consent withdrawal will be erased or permanently anonymized, unless its erasure conflicts with a legal obligation to retain such data (e.g., Product and/or Algorithms are registered as medical devices).

Who will access your data

In this context, your samples will be collected by the hospital/laboratory and tested by MASMEC and/or MSB and their providers.

MSB/MASMEC may also avail of IT service providers for the storage and transmission of Your personal data.

All such providers shall be contractually bound to implement high level security measures in order to protect your personal data to the best possible standards, commensurate with their sensitivity.

Internally, MSB will make this data available to its research staff, and other staff that may need to access that data in the context of their professional duties (e.g., administrative staff, IT staff, etc.). Staff members may also be based at the US subsidiary of MSB (Menarini Silicon Biosystems Inc.), which will process your data in line with this information notice.

The results may be reviewed by experts that will double-check their accuracy and reliability. The results may also be used for specialized publications. In both cases, you will not be identifiable.

The results will also be included in the dossier of the Product and Algorithms, and shared with regulators at their request, when prescribed by the applicable laws - e.g., pursuant to Article 10, IVDD Regulation.

All recipients of your data located outside the European Union, in countries that do not protect the right to privacy to a level comparable to that afforded by EU law will be bound to ensure an adequate level of protection of your personal data. This will be ensured by means of model contractual clauses, approved by the EU Commission, which MSB will conclude with the non-EU recipients (a copy of which is available on request). However, regulators outside the EU, where the Product that we are testing might be registered, may need to access your data if this is necessary to ensure the Product meets the quality requirements mandated by the law. In this case, your data will be processed in line with the laws of the countries where the regulators are based, and may not cover the full set of rights afforded by EU laws – e.g., the right to access or rectify your data. Even in this case, however, the regulators will not access your name, but only a code.

Retention of your data for the Project

Your personal data and biological samples will be processed in compliance with the principles of proportionality, data minimization, and storage limitation, pursuant to Article 5(1)(e) of GDPR.

The processing will continue for a period of 25 years from the date of data collection. This retention period has been established by taking into account the operational lifecycle of the developed solutions — structured as 5 years for development and validation activities, 15 years for the subsequent operational use, technical support and performance monitoring, debugging, post-marketing surveillance (including change management and corrective and preventive actions), 5-year for the management of the end of life of the solutions -including troubleshooting and technical support for the last tools placed on the market. .

The overall retention period also takes into consideration any applicable regulatory obligations that may arise in the event of certification as an in vitro diagnostic medical device, in accordance with Article 10 of Regulation (EU) 2017/746.

At the end of this period, the data will be either erased or permanently anonymized, unless legal obligations require further retention for compatible purposes.

Your rights

In line with arts. 15-22 GDPR you have the right to know what data is being processed by MSB, including where your data is located, obtain a copy of your data, as well as to rectify your data, ask that it is erased, object to its processing. You may also restrict the possibility that your samples are shared with any of the recipients or categories of recipients indicated above, I the sections “who will access your data” and “additional research projects.”

You may withdraw the consents you have conferred (including the one for the further use of samples) at any time – in this case, data about you will be erased, unless it is necessary to keep it for regulatory purposes or to ensure the results of the research are not altered.

You may exercise your rights or complain with MSB and/or MASMEC about the processing of your data by contacting them and MSB’s DPO at the addresses stated above. However, since MSB is not

able to identify you, we invite you to contact the hospital/laboratory that collected your sample at the contact details provided by them; they will forward your request to MSB and/or MASMEC using your patient code (and not your identifying information). By contacting the Joint Controllers at the above addressed, you may also obtain the terms of the joint controllership agreement between them.

Finally, You may also lodge a complaint to the Italian Supervisory Authority in case you are not satisfied with the handling of your request.

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Having read and understood the above,

I hereby:

o Consent

o Do not Consent

to the processing of my personal data by MASMEC and MSB for the purposes of developing the Product and Algorithms, under the terms described above, including any transfers to non-EU countries. Refusing to provide consent will have no consequences on my medical treatment. I understand that I may withdraw my consent at any time.

Date Patient Signature

_____ _____

I, _____

[title, name, and surname of healthcare professional collecting the sample] declare that I have explained to the patient the implications of donating the sample, including the potential benefits for scientific research and the risks to their privacy.

Healthcare Professional Signature

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