Biostarks

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BIOSTARKS – REGULATORY STATEMENT

1 - Purpose of this document

This document is intended to clarify the regulatory status of the Biostarks product in regards to Regulation (EU) 2017/745 (Medical Device Regulation MDR) and Regulation (EU) 2017/746 (In-Vitro Diagnostic Regulation IVDR).

2 - General product description

The Biostarks product consists of the following elements:

- Sample collection kit
- Laboratory analysis
- Biostarks results platform

The Biostarks tests measure the level of 25+ (depending on type of test) different micronutrient biomarkers, such as vitamins and minerals, in the blood.

Blood samples are collected at home by the customer using the sample collection kit. The samples are delivered to the laboratories and analyzed. Results are provided to the customer via the Biostarks app.

The results delivered by the Biostarks tests are intended to be used for general wellbeing purposes. The results are not intended to be used for any clinical decisions.

3 - Regulatory assessment

3.1 Sample collection kit

The sample collection kit is used by customers at home to draw small capillary blood samples from the finger. The blood samples are then sent to the laboratory for analysis.

The sample collection kits consist of the following components:

- Blood separation device or blood collection card
    - Intended for collecting and transporting (dried) blood samples
- Lancet

    - Intended for blood collection from the fingertip
- Alcohol pad
    - Intended for cleaning intact skin before punctures
- Gauze
    - Intended for cleansing, scrubbing, and covering a variety of wounds
- Plaster
    - Intended to protect a small wound from friction, bacteria, damage and dirt

All components that are CE marked medical devices or IVD medical devices are used according to the intended use as specified by the manufacturer.

The sample collection kit placed on the market by Biostarks is not considered a medical device, IVD medical device or procedure pack.

3.1.1 Regulatory background and rational

The laboratory analysis performed by Biostarks using the blood samples collected with these kits is not considered an IVD device (see section 3.2). Accordingly, the blood collection is not performed for a medical purpose. The sample collection kit is thus not considered a medical device or IVD medical device.

MDR article 22 states that procedure packs are medical devices combined with (among other products) IVD medical devices in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers. MDR Article 2(10) defines ''procedure packs' *as a combination of products packaged together and placed on the market* ***with the purpose of being used for a specific medical purpose.*** Biostarks sample collection kits are not intended for a specific medical purpose, but to draw and deliver blood samples for a lab analysis intended for wellness and lifestyle purposes only. Thus, the sample collection kits do not fulfil the definition of ''procedure pack'.

3.2 Laboratory analysis

The blood samples are analyzed on an automated platform using chemical and immunological methods, incl. high-resolution mass spectrometry combined with clinical chemistry, liquid chromatography and inductively coupled plasma mass spectrometry, to determine the level of several micronutrient biomarkers in the blood.

The laboratory analysis of biomarkers and required equipment does not qualify as an IVD medical device. The information provided by the analysis is not intended to be used for a specific medical purpose but for wellbeing purposes exclusively.

3.2.1 Regulatory background and rational

IVD devices are regulated by Regulation (EU) 2017/746 (In-Vitro Diagnostic Regulation IVDR). The definition of an IVD is given in Article 2(2) of the IVDR:

> *'in vitro diagnostic medical device' means any **medical device** which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:*
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> *a) concerning a physiological or pathological process or state;*
> *b) concerning congenital physical or mental impairments;*
> *c) concerning the predisposition to a medical condition or a disease;*
> *d) to determine the safety and compatibility with potential recipients;*
> *e) to predict treatment response or reactions;*
> *f) to define or monitoring therapeutic measures.*
> *[...]*

For a device to fulfil this definition, it must first fulfil the definition of **medical device**, which is given in Article 2(1) of Regulation (EU) 2017/745 (Medical Device Regulation MDR):

> *'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following **specific medical purposes**:*
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> – *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
> – *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
> – *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
> – ***providing information by means of in vitro examination of specimens derived from the human body**, including organ, blood and tissue donations, [...]*

Importantly, not all devices that provide *'information by means of in vitro examination of specimens derived from the human body'* are considered medical devices. Tests for substance/alcohol abuse, paternity tests, ancestry tests, etc. provide information by means of in vitro examinations of samples from the human body but are not considered

medical devices. Consequently, the provision of '*information by means of in vitro examination of specimens derived from the human body*' does not in itself constitute a '*specific medical purpose'*. The provided information itself would need to be used to serve a specific medical purpose for the definition of 'medical device' to apply.

As the information provided by the Biostarks micronutrient biomarker level analysis is not intended for any specific medical purpose such as diagnosis, monitoring, etc., the definition of 'medical device' according to MDR Article 2(1) is not fulfilled. The Biostarks laboratory analysis thus does not qualify as a medical device and consequently not as an IVD medical device.

In addition, MDCG 2024-11 states:

Products without a medical purpose (as outlined in Article 2(2) IVDR) are not IVDs. Examples: tests to determine ancestry, to find relatives, or to reveal ethnic origins, or tests intended to be used for sport, wellbeing and lifestyle purposes.

3.3 Biostarks results platform

The Biostarks results platform is primarily intended to display the results of the laboratory analysis. Additionally, the platform displays 'Benefit Verticals' (specific benefit verticals associated with each biomarker, such as 'Sleep Quality', 'Mood', 'Skin/Hair/Nail Appearance', etc.), recommended ranges for each biomarker based on established literature, and food recommendations related to biomarkers that are out of range.

The Biostarks app does not qualify as a medical device (i.e. medical device software MDSW), as it does not analyze, create or modify any medical information

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3.3.1 Regulatory background and rational

MDCG 2019-11 'Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR' provides assistance for the qualification of software as a medical device (Medical Device Software MDSW).

According to step 3 of the decision tree in MDCG 2019-11, software that performs processes on data limited to storage, archival, communication, simple search or lossless compression is not considered to qualify as a medical device.

The Biostarks app does not process any relevant data other than communicating it to the customer and performing simple searches to deliver related information. In addition, as the Biostarks laboratory analysis is not considered an IVD medical device, the information provided by the tests and processed by the app is not considered

medical data. The Biostarks app therefore does not fulfil the definition of MDSW according to MDCG 2019-11.

4 – References

[1] Regulation (EU) 2017/745 on Medical Devices (MDR)

[2] Regulation (EU) 2017/746 on In-Vitro Diagnostic Devices (IVDR)

[3] Guidance on qualification and classification of software MDCG 2019-11

[4] Guidance on qualification of in vitro diagnostic medical devices MDCG 2024-11

5 – Assessment Confirmation

This regulatory assessment has been conducted by ISS AG in Switzerland.

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Regulatory Copliance Expert

ISS AG, Integrated Scientific Services, 23.10.2024

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