Aleksandra Kostrzewa
name and surname

.....
address

In connection with:
☐ participation in the audit.....(audit number and date) for the device.....manufactured by.....contract no.....
☐ assessment of the technical documentation for the device.....manufactured by.....contract no.....
☒ management contract

I declare that:

- I am not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which I assesses, nor the authorised representative of any of those parties. I am aware that such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- I am not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which I am designated, nor I do not represent the parties engaged in those activities;
- I do not engage in any activity that may conflict with my independence of judgement or integrity in relations to conformity assessment activities for which I am designated;
- I do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacture, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment; and
- I am not linked to any organisation which itself provides consultancy services as referred to in bullet tiret above. Such restriction does not preclude general Training activities that are not client specific and that relate to regulation of devices or to related standards;
- I have not provided and offered services to the manufacturer or his business competitor as well as I have not maintained business and/or personal relationships with their personnel/familiar/ associates/ employees;
- I have not received any (financial/personal) benefits from the manufacturer or his business competitor;
- I have not conducted clinical trials as: a sponsor/ investigator /co-investigator /trial coordinator/ monitor for the manufacturer (this restriction shall not apply to teaching and statutory activities of the parent entity in which the expert/auditor is employed);
- I have not conducted dedicated training on medical devices intended for the manufacturer, his authorised representative, supplier nor business competitor;
- I have not been personally involved in the business conducted by the manufacturer, I have not been involved financially, formally and legally, as a member of the body or as a venture of the manufacturer nor his business competitor;

- I have not had receivables nor financial liabilities towards the manufacturer nor his business competitor;
- I have not provided sureties or other claim collaterals towards the manufacturer nor his business competitor;
- I have not been in a legal/ personal dispute with the manufacturer nor his business competitor;
- I have not run any activity competitive to the manufacturer.

At the same time, I declare that there are no circumstances (other not listed above) that could indicate a conflict of interest between me and the manufacturer.

Furthermore, I declare that I have read the applicable documentation of the BM Department available via the FTP server.

I undertake to:

- Represent the PCBC worthily within assigned tasks;
- Perform all activities based on independence, impartiality and reliability
- Preserve the confidentiality of the information obtained in performing conformity assessment activities for an unlimited duration, in particular about:
  - certified medical devices,
  - quality assurance system of the manufacturer of the medical device and/or his subcontractor,
  - running, conclusions and outcome of the medical device conformity assessment procedure;
- Preserve the confidentiality with regard to all information obtained in performing tasks for an unlimited duration, except for the disclosure to designating authorities, competent bodies or the European Commission, or where disclosure of information is required by law;
- Preserve the confidentiality for an unlimited duration and not to disclose available information regarding the PCBC, clients to whom I will have access due to the performance of the Contract concluded with the PCBC, and not intended by the PCBC to be disseminated, without the consent of the PCBC, during the Contract period and after the contractual period;
- Report and update (on the Data Update Card form) all former and current business or/and other relations, including personal relations with medical device manufacturers, their personnel, authorized representatives, suppliers, as well as business competitors, and other information referred to in this Statement;
- Report any situations, not listed above, of potential conflict of interest between me and the manufacturer involved in the conformity assessment activities;
- Follow the procedures determined by the PCBC.

I undertake to return to the PCBC or erasure permanently all materials made available and provided by the PCBC under the aforementioned Contract from electronic storage media.

Furthermore, I declare that I am aware that the disclosure of data I acquire performing activities for the PCBC within conformity assessment constitutes an act of unfair competition, under Art. 11 of the Act on fight against unfair competition, that could carry criminal liability.

President

Aleksandra Kostrzewa

Warsaw, 01.03.2023
Place and date

.....
Signature

Paulina Pietrasik-Stippa
name and surname

.....
address

In connection with:
☐ participation in the audit.....(audit number and date) for the device.....manufactured by.....contract no.....
☐ assessment of the technical documentation for the device.....manufactured by.....contract no.....
☒ management contract

I declare that:

- I am not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which I assesses, nor the authorised representative of any of those parties. I am aware that such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- I am not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which I am designated, nor I do not represent the parties engaged in those activities;
- I do not engage in any activity that may conflict with my independence of judgement or integrity in relations to conformity assessment activities for which I am designated;
- I do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacture, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment; and
- I am not linked to any organisation which itself provides consultancy services as referred to in bullet tiret above. Such restriction does not preclude general Training activities that are not client specific and that relate to regulation of devices or to related standards;
- I have not provided and offered services to the manufacturer or his business competitor as well as I have not maintained business and/or personal relationships with their personnel/familiar/ associates/ employees;
- I have not received any (financial/personal) benefits from the manufacturer or his business competitor;
- I have not conducted clinical trials as: a sponsor/ investigator /co-investigator /trial coordinator/ monitor for the manufacturer (this restriction shall not apply to teaching and statutory activities of the parent entity in which the expert/auditor is employed);
- I have not conducted dedicated training on medical devices intended for the manufacturer, his authorised representative, supplier nor business competitor;
- I have not been personally involved in the business conducted by the manufacturer, I have not been involved financially, formally and legally, as a member of the body or as a venture of the manufacturer nor his business competitor;

- I have not had receivables nor financial liabilities towards the manufacturer nor his business competitor;
- I have not provided sureties or other claim collaterals towards the manufacturer nor his business competitor;
- I have not been in a legal/ personal dispute with the manufacturer nor his business competitor;
- I have not run any activity competitive to the manufacturer.

At the same time, I declare that there are no circumstances (other not listed above) that could indicate a conflict of interest between me and the manufacturer.

Furthermore, I declare that I have read the applicable documentation of the BM Department available via the FTP server.

I undertake to:

- Represent the PCBC worthily within assigned tasks;
- Perform all activities based on independence, impartiality and reliability
- Preserve the confidentiality of the information obtained in performing conformity assessment activities for an unlimited duration, in particular about:
  - certified medical devices,
  - quality assurance system of the manufacturer of the medical device and/or his subcontractor,
  - running, conclusions and outcome of the medical device conformity assessment procedure;
- Preserve the confidentiality with regard to all information obtained in performing tasks for an unlimited duration, except for the disclosure to designating authorities, competent bodies or the European Commission, or where disclosure of information is required by law;
- Preserve the confidentiality for an unlimited duration and not to disclose available information regarding the PCBC, clients to whom I will have access due to the performance of the Contract concluded with the PCBC, and not intended by the PCBC to be disseminated, without the consent of the PCBC, during the Contract period and after the contractual period;
- Report and update (on the Data Update Card form) all former and current business or/and other relations, including personal relations with medical device manufacturers, their personnel, authorized representatives, suppliers, as well as business competitors, and other information referred to in this Statement;
- Report any situations, not listed above, of potential conflict of interest between me and the manufacturer involved in the conformity assessment activities;
- Follow the procedures determined by the PCBC.

I undertake to return to the PCBC or erasure permanently all materials made available and provided by the PCBC under the aforementioned Contract from electronic storage media.

Furthermore, I declare that I am aware that the disclosure of data I acquire performing activities for the PCBC within conformity assessment constitutes an act of unfair competition, under Art. 11 of the Act on fight against unfair competition, that could carry criminal liability.

Member of the Board
Paulina Pietrasik-Stippa

Warsaw, 01.03.2023
Place and date

.....
Signature

Tomasz Koeber
name and surname

.....
address

In connection with:
☐ participation in the audit.....(audit number and date) for the device.....manufactured by.....contract no.....
☐ assessment of the technical documentation for the device.....manufactured by.....contract no.....
☒ performing professional duties as a PCBC employee (employment contract)

I declare that:

- I am not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which I assesses, nor the authorised representative of any of those parties. I am aware that such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- I am not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which I am designated, nor I do not represent the parties engaged in those activities;
- I do not engage in any activity that may conflict with my independence of judgement or integrity in relations to conformity assessment activities for which I am designated;
- I do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacture, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment; and
- I am not linked to any organisation which itself provides consultancy services as referred to in bullet tiret above. Such restriction does not preclude general Training activities that are not client specific and that relate to regulation of devices or to related standards;
- I have not provided and offered services to the manufacturer or his business competitor as well as I have not maintained business and/or personal relationships with their personnel/familiar/ associates/ employees;
- I have not received any (financial/personal) benefits from the manufacturer or his business competitor;
- I have not conducted clinical trials as: a sponsor/ investigator /co-investigator /trial coordinator/ monitor for the manufacturer (this restriction shall not apply to teaching and statutory activities of the parent entity in which the expert/auditor is employed);
- I have not conducted dedicated training on medical devices intended for the manufacturer, his authorised representative, supplier nor business competitor;
- I have not been personally involved in the business conducted by the manufacturer, I have not been involved financially, formally and legally, as a member of the body or as a venture of the manufacturer nor his business competitor;

- I have not had receivables nor financial liabilities towards the manufacturer nor his business competitor;
- I have not provided sureties or other claim collaterals towards the manufacturer nor his business competitor;
- I have not been in a legal/ personal dispute with the manufacturer nor his business competitor;
- I have not run any activity competitive to the manufacturer.

At the same time, I declare that there are no circumstances (other not listed above) that could indicate a conflict of interest between me and the manufacturer.

Furthermore, I declare that I have read the applicable documentation of the BM Department available via the FTP server.

I undertake to:

- Represent the PCBC worthily within assigned tasks;
- Perform all activities based on independence, impartiality and reliability
- Preserve the confidentiality of the information obtained in performing conformity assessment activities for an unlimited duration, in particular about:
  - certified medical devices,
  - quality assurance system of the manufacturer of the medical device and/or his subcontractor,
  - running, conclusions and outcome of the medical device conformity assessment procedure;
- Preserve the confidentiality with regard to all information obtained in performing tasks for an unlimited duration, except for the disclosure to designating authorities, competent bodies or the European Commission, or where disclosure of information is required by law;
- Preserve the confidentiality for an unlimited duration and not to disclose available information regarding the PCBC, clients to whom I will have access due to the performance of the Contract concluded with the PCBC, and not intended by the PCBC to be disseminated, without the consent of the PCBC, during the Contract period and after the contractual period;
- Report and update (on the Data Update Card form) all former and current business or/and other relations, including personal relations with medical device manufacturers, their personnel, authorized representatives, suppliers, as well as business competitors, and other information referred to in this Statement;
- Report any situations, not listed above, of potential conflict of interest between me and the manufacturer involved in the conformity assessment activities;
- Follow the procedures determined by the PCBC.

I undertake to return to the PCBC or erasure permanently all materials made available and provided by the PCBC under the aforementioned Contract from electronic storage media.

Furthermore, I declare that I am aware that the disclosure of data I acquire performing activities for the PCBC within conformity assessment constitutes an act of unfair competition, under Art. 11 of the Act on fight against unfair competition, that could carry criminal liability.

Warsaw, 26.09.2022
Place and date

Tomasz Kobb
.....
Signature

Agnieszka Bukowska
name and surname

.....
address

In connection with:
☐ participation in the audit.....(audit number and date) for the device.....manufactured by.....contract no.....
☐ assessment of the technical documentation for the device.....manufactured by.....contract no.....
☒ performing professional duties as a PCBC employee (employment contract)

I declare that:

- I am not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which I assesses, nor the authorised representative of any of those parties. I am aware that such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- I am not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which I am designated, nor I do not represent the parties engaged in those activities;
- I do not engage in any activity that may conflict with my independence of judgement or integrity in relations to conformity assessment activities for which I am designated;
- I do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacture, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment; and
- I am not linked to any organisation which itself provides consultancy services as referred to in bullet tiret above. Such restriction does not preclude general Training activities that are not client specific and that relate to regulation of devices or to related standards;
- I have not provided and offered services to the manufacturer or his business competitor as well as I have not maintained business and/or personal relationships with their personnel/familiar/ associates/ employees;
- I have not received any (financial/personal) benefits from the manufacturer or his business competitor;
- I have not conducted clinical trials as: a sponsor/ investigator /co-investigator /trial coordinator/ monitor for the manufacturer (this restriction shall not apply to teaching and statutory activities of the parent entity in which the expert/auditor is employed);
- I have not conducted dedicated training on medical devices intended for the manufacturer, his authorised representative, supplier nor business competitor;
- I have not been personally involved in the business conducted by the manufacturer, I have not been involved financially, formally and legally, as a member of the body or as a venture of the manufacturer nor his business competitor;

- I have not had receivables nor financial liabilities towards the manufacturer nor his business competitor;
- I have not provided sureties or other claim collaterals towards the manufacturer nor his business competitor;
- I have not been in a legal/ personal dispute with the manufacturer nor his business competitor;
- I have not run any activity competitive to the manufacturer.

At the same time, I declare that there are no circumstances (other not listed above) that could indicate a conflict of interest between me and the manufacturer.

Furthermore, I declare that I have read the applicable documentation of the BM Department available via the FTP server.

I undertake to:

- Represent the PCBC worthily within assigned tasks;
- Perform all activities based on independence, impartiality and reliability
- Preserve the confidentiality of the information obtained in performing conformity assessment activities for an unlimited duration, in particular about:
  - certified medical devices,
  - quality assurance system of the manufacturer of the medical device and/or his subcontractor,
  - running, conclusions and outcome of the medical device conformity assessment procedure;
- Preserve the confidentiality with regard to all information obtained in performing tasks for an unlimited duration, except for the disclosure to designating authorities, competent bodies or the European Commission, or where disclosure of information is required by law;
- Preserve the confidentiality for an unlimited duration and not to disclose available information regarding the PCBC, clients to whom I will have access due to the performance of the Contract concluded with the PCBC, and not intended by the PCBC to be disseminated, without the consent of the PCBC, during the Contract period and after the contractual period;
- Report and update (on the Data Update Card form) all former and current business or/and other relations, including personal relations with medical device manufacturers, their personnel, authorized representatives, suppliers, as well as business competitors, and other information referred to in this Statement;
- Report any situations, not listed above, of potential conflict of interest between me and the manufacturer involved in the conformity assessment activities;
- Follow the procedures determined by the PCBC.

I undertake to return to the PCBC or erasure permanently all materials made available and provided by the PCBC under the aforementioned Contract from electronic storage media.

Furthermore, I declare that I am aware that the disclosure of data I acquire performing activities for the PCBC within conformity assessment constitutes an act of unfair competition, under Art. 11 of the Act on fight against unfair competition, that could carry criminal liability.

A. Bukowska

Warsaw, 26.09.2022
Place and date

.....
Signature

Agnieszka Sarzała
name and surname

.....
address

In connection with:
☐ participation in the audit.....(audit number and date) for the device.....manufactured by.....contract no.....
☐ assessment of the technical documentation for the device.....manufactured by.....contract no.....
☒ performing professional duties as a PCBC employee (employment contract)

I declare that:

- I am not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which I assesses, nor the authorised representative of any of those parties. I am aware that such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- I am not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which I am designated, nor I do not represent the parties engaged in those activities;
- I do not engage in any activity that may conflict with my independence of judgement or integrity in relations to conformity assessment activities for which I am designated;
- I do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacture, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment; and
- I am not linked to any organisation which itself provides consultancy services as referred to in bullet tiret above. Such restriction does not preclude general Training activities that are not client specific and that relate to regulation of devices or to related standards;
- I have not provided and offered services to the manufacturer or his business competitor as well as I have not maintained business and/or personal relationships with their personnel/familiar/ associates/ employees;
- I have not received any (financial/personal) benefits from the manufacturer or his business competitor;
- I have not conducted clinical trials as: a sponsor/ investigator /co-investigator /trial coordinator/ monitor for the manufacturer (this restriction shall not apply to teaching and statutory activities of the parent entity in which the expert/auditor is employed);
- I have not conducted dedicated training on medical devices intended for the manufacturer, his authorised representative, supplier nor business competitor;
- I have not been personally involved in the business conducted by the manufacturer, I have not been involved financially, formally and legally, as a member of the body or as a venture of the manufacturer nor his business competitor;

- I have not had receivables nor financial liabilities towards the manufacturer nor his business competitor;
- I have not provided sureties or other claim collaterals towards the manufacturer nor his business competitor;
- I have not been in a legal/ personal dispute with the manufacturer nor his business competitor;
- I have not run any activity competitive to the manufacturer.

At the same time, I declare that there are no circumstances (other not listed above) that could indicate a conflict of interest between me and the manufacturer.

Furthermore, I declare that I have read the applicable documentation of the BM Department available via the FTP server.

I undertake to:

- Represent the PCBC worthily within assigned tasks;
- Perform all activities based on independence, impartiality and reliability
- Preserve the confidentiality of the information obtained in performing conformity assessment activities for an unlimited duration, in particular about:
  - certified medical devices,
  - quality assurance system of the manufacturer of the medical device and/or his subcontractor,
  - running, conclusions and outcome of the medical device conformity assessment procedure;
- Preserve the confidentiality with regard to all information obtained in performing tasks for an unlimited duration, except for the disclosure to designating authorities, competent bodies or the European Commission, or where disclosure of information is required by law;
- Preserve the confidentiality for an unlimited duration and not to disclose available information regarding the PCBC, clients to whom I will have access due to the performance of the Contract concluded with the PCBC, and not intended by the PCBC to be disseminated, without the consent of the PCBC, during the Contract period and after the contractual period;
- Report and update (on the Data Update Card form) all former and current business or/and other relations, including personal relations with medical device manufacturers, their personnel, authorized representatives, suppliers, as well as business competitors, and other information referred to in this Statement;
- Report any situations, not listed above, of potential conflict of interest between me and the manufacturer involved in the conformity assessment activities;
- Follow the procedures determined by the PCBC.

I undertake to return to the PCBC or erasure permanently all materials made available and provided by the PCBC under the aforementioned Contract from electronic storage media.

Furthermore, I declare that I am aware that the disclosure of data I acquire performing activities for the PCBC within conformity assessment constitutes an act of unfair competition, under Art. 11 of the Act on fight against unfair competition, that could carry criminal liability.

Warsaw, 26.09.2022
Place and date

.....
Signature

Izabela Czeluśniak
name and surname

.....
address

In connection with:

☐ participation in the audit.....(audit number and date) for the device.....manufactured by.....contract no.....
☐ assessment of the technical documentation for the device.....manufactured by.....contract no.....
☒ performing professional duties as a PCBC employee (emplyment contract)

I declare that:

- I am not the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which I assesses, nor the authorised representative of any of those parties. I am aware that such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- I am not involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which I am designated, nor I do not represent the parties engaged in those activities;
- I do not engage in any activity that may conflict with my independence of judgement or integrity in relations to conformity assessment activities for which I am designated;
- I do not offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacture, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment; and
- I am not linked to any organisation which itself provides consultancy services as referred above. Such restriction does not preclude general Training activities that are not Manufacturer specific and that relate to regulation of devices or to related standards;
- I have not provided and offered services to the manufacturer or his business competitor as well as I have not maintained business and/or personal relationships with their personnel/familiar/ associates/ employees;
- I have not received any (financial/personal) benefits from the manufacturer or his business competitor;
- I have not conducted clinical trials as: a sponsor/ investigator /co-investigator /trial coordinator/ monitor for the manufacturer (this restriction shall not apply to teaching and statutory activities of the parent entity in which the expert/auditor is employed);
- I have not conducted dedicated training on medical devices/in vitro diagnostic medical devices intended for the manufacturer, his authorised representative, supplier nor business competitor;
- I have not been personally involved in the business conducted by the manufacturer, I have not been involved financially, formally and legally, as a member of the body or as a venture of the manufacturer nor his business competitor;

- I have not had receivables nor financial liabilities towards the manufacturer nor his business competitor;
- I have not provided sureties or other claim collaterals towards the manufacturer nor his business competitor;
- I have not been in a legal/ personal dispute with the manufacturer nor his business competitor;
- I have not run any activity competitive to the manufacturer.

At the same time, I declare that there are no circumstances (other not listed above) that could indicate a conflict of interest between me and the manufacturer.

Furthermore, I declare that I have read the applicable documentation of the BM Department available via the FTP server.

I undertake to:

- Represent the PCBC worthily within assigned tasks;
- Perform all activities based on independence, impartiality and reliability
- Preserve the confidentiality of the information obtained in performing conformity assessment activities for an unlimited duration, in particular about:
  - certified medical devices/in vitro diagnostic medical devices,
  - quality assurance system of the manufacturer of the medical device/in vitro diagnostic medical device and/or his subcontractor,
  - running, conclusions and outcome of the medical device/in vitro diagnostic medical device conformity assessment procedure;
- Preserve the confidentiality with regard to all information obtained in performing tasks for an unlimited duration, except for the disclosure to designating authorities, competent bodies or the European Commission, or where disclosure of information is required by law;
- Preserve the confidentiality for an unlimited duration and not to disclose available information regarding the PCBC, Manufacturers to whom I will have access due to the performance of the Contract concluded with the PCBC, and not intended by the PCBC to be disseminated, without the consent of the PCBC, during the Contract period and after the contractual period;
- Report and update (on the Data Update Card form) all former and current business or/and other relations, including personal relations with medical device/in vitro diagnostic medical device manufacturers, their personnel, authorized representatives, suppliers, as well as business competitors, and other information referred to in this Statement;
- Report any situations, not listed above, of potential conflict of interest between me and the manufacturer involved in the conformity assessment activities;
- Follow the procedures determined by the PCBC.

I undertake to return to the PCBC or erasure permanently all materials made available and provided by the PCBC under the aforementioned Contract from electronic storage media.

Furthermore, I declare that I am aware that the disclosure of data I acquire performing activities for the PCBC within conformity assessment constitutes an act of unfair competition, under Art. 11 of the Act on fight against unfair competition, that could carry criminal liability.

Warsaw, 02.04.2024
Place and date

Izabela Celuszniak
.....
Signature