To Whom It May Concern

Innomed Service Policy based on MDR requirements

Communication method

We kindly ask you to use our Error Reporting Form in all cases when you have problem with our devices to support our customer service with this important information for your benefit.
By using this form we expect the increase of our customer service efficiency and we will meet also the growing requirements of the legal environment.

Competency

Service activity should be performed only by person authorized by local law with appropriate permissions, competences and based on knowledge of the relevant service manual and all belonging technical information. Ensuring the level of knowledge actualities, changes, best practices will continuously be shared by email.

Responsibility

The service activity is technically supported by Innomed Medical Zrt. if needed, however it will not be controlled directly.

If replacement part is required during the service activity, the defective part under warranty service should be sent back to Innomed by courier for further technical investigation which is handled as a customer's property. For the repairs you must apply the tools and equipments or their compatible versions listed in the relevant Measurement Test Report or shall be used the original service manual of the device. Measurements, including safety and functional tests must be done all cases when the device is opened for repairing. The results of the measurements must be checked and the document must be signed.

Feedback

Filled in „Measurement Test Report" should be sent to our customer service in all cases after completing the service activity. The measurement test report must contain additional detailed information about the repair itself and the results of the test measurements performed indicating the serial numbers of the removed and replacement parts as well.

Post market activities

To fulfil our legal / MDR requirements we must receive the following data in every year till end of January relating to the previous year in a well-structured searchable xls form as described in the table below:

- Number of the faulty devices by type
- Typical failure types by device
- The most common failure part of the device
- Declare if the event can be considered as a Serious Incident* or not in the reported year.

ID	Device type	Device SN	Failure modes	Failure part	Failure part SN	Serious Incident

* Serious Incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:
- the death of a patient, user, or other person,
- the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health,
- a serious public health threat.

Closing word

The listed documents are available and can be downloaded from Innomed Medical Zrt Extranet webpage: https://extranet.innomed.hu/

- Service requirements document for new and current partners also
- Yearly report template xls file
- Service manuals by devices containing the measurement reports
- Specific test reports by devices (Annual service report.xls file)

Date and place

Distributor

Signature