Annex 4 – Challenge Template

1. **Name of the challenge:**

Methodology for Defying the Class of a Medical Device and the Common Requirements it Should Meet According to Regulation 2017/745

2. **Context:**

Manufacturers of medical device are obliged by the current legislation: Council Directive 93/42 and will be by the upcoming regulation 2017/745 to assess the conformity of their products according to the mentioned normative acts. This is done by choosing the right conformity assessment procedures. The choice is determined by defining the class of the medical device, which is done by means of the classification rules. Practice shows that those rules are found to be in a way too abstract, so the manufacturer cannot understand their application in an adequate way. The same could be stated for the official manual guides, so classification of medical device is considered an important issue. Similar issues occurs when determining the adequate application of common requirements to a particular medical device.

3. **Problem:**

A solution to these problems is provided by developing a methodology for determining the class of the medical product and the common requirements that it should satisfy. With this methodology, the necessary initial information is obtained in a clear and certain confident way, so the collection of the documentation necessary for the establishment of the content of a technical file follows clear rules. For establishing this methodology, medical devices are divided into three domains: groups, types and sorts. The relationships between them is described in a logical model that finds its expression in a block diagram following certain algorithm, which can be manifested in practice incorporated in a relational data base system. This endeavor sets the foundation for the developing of a comprehensive system for complete normative providing of medical device products.

4. **Additional info (for internal use):**

The team has to offer a methodology for defying the class of a medical device and the common requirements according to regulation 2017/745.

5. **Skills of the team (for internal use):**

Basic knowlege in mechanical engineering, European technical legislation

Basic information, additional information
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and standardization, medical devices.

6. About the Seeker:

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