**Technical Description AI Model** **<Model name>**

**(Version X of DD.MM.YYYY)**

1. **Manufacturer Information**

|  |  |
| --- | --- |
| **Manufacturer** |  |
| **SRN** |  |
| **Responsible Person** |  |

1. **Description and Specification of Medical Device**

|  |  |
| --- | --- |
| **Medical Device  (Trade Name)** |  |
| **Basic UDI-DI** |  |
| **UDI (UDI-DI + UDI-PI)** |  |
| **CND Code(s)** |  |
| **General Description** |  |
| **Accessories** |  |

1. **Model details**

|  |  |
| --- | --- |
| **Version** |  |
| **Type** |  |
| **Intended purpose** |  |
| **Main purpose** |  |
| **Autonomy** |  |
| **Programming language (version)** |  |
| **Framework / libraries (version)** |  |
| **Status** |  |
| **Input data (source/type)** |  |
| **Patient target group** |  |

1. **Hardware**

|  |  |
| --- | --- |
| **Hardware 1** |  |
| **Hardware 2** |  |
| **Hardware 3** |  |

1. **Clinical benefit**

|  |  |
| --- | --- |
| **Benefit 1** |  |
| **Benefit 2** |  |
| **Benefit 3** |  |

1. **Results of testing and evaluation**

|  |  |
| --- | --- |
| **Confusion matrix** |  |
| **Selected quality measures** |  |
| **Comparison to gold standard** |  |

1. **Model development**

|  |  |
| --- | --- |
| **Data acquisition site** |  |
| **Data acquisition system** |  |
| **General description** |  |
| **Amount training data** |  |
| **Amount tuning data** |  |
| **Amount test data** |  |

1. **Residual risks**

|  |  |
| --- | --- |
| **Residual Risk 1** |  |
| **Residual Risk 2** |  |
| **Residual Risk 3** |  |

1. **Additional information**

|  |  |
| --- | --- |
| **Webpage** |  |
| **How to contact us (Support)** |  |
| **Publication** |  |

1. **Approval**

I approve the present version of the document.

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Place, Date Title, first name, last name

Function

Company