Universität Basel

Departement Klinische Forschung

Universitätsspital Basel

MD-01 Declaration of Conformity

Confluence space / project:

MS Lesion Segmentation Algorithm (MS-MD-GRU)

Status: **APPROVED**

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1 Document Properties

Company Name	University Hospital and University of Basel
Status	APPROVED
Version	1
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Author	@ Claudia Saupper
Reviewer	@ Claudia Becherer
Approver	@ Roland John @ Philippe C. Cattin @ Johanna Lieb

1.1 Document Approval

Approver	Status	Approval Date
Philippe C. Cattin	APPROVED	Monday 28 Oct 2024, UTC
Roland John	APPROVED	Monday 21 Oct 2024, UTC
Claudia Saupper	APPROVED	Monday 21 Oct 2024, UTC
Johanna Lieb	APPROVED	Friday 25 Oct 2024, UTC
Claudia Becherer	APPROVED	Friday 25 Oct 2024, UTC

2 Declaration of Conformity

Name of health institution	**University Hospital and University of Basel**
Address	Petersgraben 4, 4031 Basel

University Hospital and University of Basel declares that the below mentioned device meets all the provisions of the Swiss Medical Device Ordinance (MedDO) 812.213 and European Medical Device Regulation (MDR) 2017/745, which apply to it.

Medical device(s)	**MS Lesion Segmentation Algorithm (MS-MD-GRU)**
Basic UDI-DI	n/a
Intended Purpose	The **MS-MD-GRU** is a computer system intended for performing automated lesion segmentation to support the monitoring and treatment decision-making of multiple sclerosis (MS) disease patients. The analysis is performed utilizing MRI brain scans which have to be taken with an acquisition protocol as defined by University Hospital Basel (USB). This software is intended to automate the manual process of identifying and labeling brain lesions on MR images. **MS-MD-GRU** is compatible with the DICOM standard and its transfer protocol. The output is a DICOM segmentation object that may be corrected by the (Neuro)-Radiologist.

Risk Class	Class IIa
Rule (according to Annex VIII)	Rule 11
General Safety and Performance Requirements (GSPR)	The device meets the GSPR

This declaration of conformity is issued under the sole responsibility of the manufacturer.	
European Authorised Representative (EC-Rep)	n/a
Single Registration Number (SRN) EC-Rep	n/a
Applied Common Specifications	On the date of issue of this document, no relevant common specifications were available
Conformity Assessment Procedure	n/a
Notified Body (if applicable)	n/a This is an in-house developed medical device and not marketed.
MDR Certificate	n/a
Additional Information (if applicable)	This medical device is submitted to Swissmedic as in-house developed medical device according to MDR Art 5(5).
Responsible Person	Johanna Lieb, Kaderärztin Radiologie
Validity of this declaration	30 Sep 2030

2.1 Product Image/ Photograph

Not applicable as this is a medical device software.

2.2 Article List

Article Number	Product Name / Registered Trade Name	Classification	Rule
MD-MD-GRU v.1.0.X	**MS Lesion Segmentation Algorithm**	Class IIa	Rule 11