EC-Certificate

SQS as a conformity assessment body identification number 1250 herewith certifies the company

McMRI AG
Acherweg 3
6370 Stans
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated December 7, 2017.

The scope of validity covers the product

appMRI Hippocampus Volume Analyser

The following CE label can be applied to the product mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Validity 30.01.2018 – 28.02.2019
Issue 30.01.2018

Reg. no. 41509
Approved Medical Responsible
30.01.2018

F. Müller, CEO SQS

D. Taddeo, Medical Responsible

sqs.ch

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland

Swiss Made

Partner of IQNet

Appendix to the EC-Certificate

ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection
with the following certificate:

Registration Number 41509

Validity from January 30, 2018 up to and including February 28, 2019

This approval includes the following Medical Device/s:

Class IIa
– appMRI Hippocampus Volume Analyser

Appendix issue date: January 30, 2018