

Report on the FCC and IC Testing of the
Sartorius Stedim Switzerland AG
RFID Module for Sterile Connection Device
Model: RFID Read-Writer
In accordance with FCC 47 CFR, § 1.1310,
and RSS-102

Prepared for: Sartorius Stedim Switzerland AG
Ringstrasse 24A
8317 Tagelswangen, Switzerland



Product Service

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Inspire trust.

COMMERCIAL-IN-CONFIDENCE

Date: 2024-04-10

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RESPONSIBLE FOR	NAME	DATE	SIGNATURE
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Authorised Signatory	Matthias Stumpe	2024-04-12	SIGN-ID 904762

Signatures in this approval box have checked this document in line with the requirements of TÜV SÜD Product Service document control rules.

Engineering Statement:

This measurement shown in this report were made in accordance with the procedures described on test pages.
All reported testing was carried out on a sample equipment to demonstrate limited compliance with FCC 47 CFR, Part 1, § 1.1310, and RSS-102 Issue 6

The sample tested was found to comply with the requirements defined in the applied rules.

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Martin Steindl	2024-04-10	SIGN-ID 904020

Laboratory Accreditation
Dakks Reg. No. D-PL-11321-11-02
Dakks Reg. No. D-PL-11321-11-03

Laboratory recognition
Registration No. BNetzA-CAB-16/21-15

Industry Canada test site registration
3050A-2

Executive Statement:

A sample of this product was tested and found to be compliant with FCC 47 CFR (October 2023), Part 1, § 1.1310, and RSS-102 Issue 5 (March 2015) + Amendment 1 (February 2021)

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1 Report Summary

1.1 Modification Report

Alternations and additions of this report will be issued to the holders of each copy in the form of a complete document.

Revision	Description of changes	Date of Issue
0	First Issue	2024-04-10

Table 1: Report of Modifications

1.2 Introduction

Applicant	Sartorius Stedim Switzerland AG Ringstrasse 24A 8317 Tagelswangen, Switzerland
Manufacturer	REED Electronics AG Gewerbering 2 6105 Schachen, Switzerland
Model Number(s)	RFID Read-Writer
Reference Number(s)	49585
Serial Number(s)	N/A
Hardware Version(s)	Product Version 50000v002
Software Version(s)	Product Version 50000v002
Number of Samples Tested	1
Test Specification(s) /	FCC 47 CFR, Part 1, § 1.1310
Issue / Date	RSS-102 Issue 5 (March 2015) + Amendment 1 (February 2021)
Test Plan/Issue/Date	2023-11-08
Order Number	2123626
Date	2023-07-26
Date of Receipt of EUT	2023-08-07
Start of Test	2023-11-10
Finish of Test	2024-04-04
Name of Engineer(s)	M. Steindl
Related Document(s)	KDB 44798 D04 Interim General RF Exposure Guidance v01 ANSI C63.10 (2013)



1.3 Brief Summary of Results

A brief summary of the tests carried out in accordance with FCC 47 CFR Part 1 I and ISED RSS-102 is shown below.

Section	Specification Clause	Test Description	Result
2.1	1.1310	RF Exposure	Pass

Table 2: Results according to FCC 47 CFR Part 1 I

Section	Specification Clause	Test Description	Result
2.1	4	RF Exposure	Pass

Table 3: Results according to ISED RSS-102



1.4 Product Information

1.4.1 Technical Description

Frequency Band: 11.81 – 15.31 MHz

Supply Voltage: 120 V

Supply Frequency: 60 Hz

1.4.2 EUT Ports / Cables identification

<i>Description</i>	<i>Classification</i>	<i>Screened</i>	<i>Length (used)</i>	<i>Length (max. specified)</i>
Mains power port	AC power port	No	3 m	3 m
Ethernet	Signal / Control port	Yes	3m	> 30 m

Table 4



1.4.3 Identification labels

Biowelder® S 1.0
Serial-No. BWS00002

Lot-No. 3121638.1
Date of manufacturing 20230616
V 100-240V~
HZ 50-60Hz, max. 280VA
IP IP 2X
Fuse 2 x 3.15AT H,250V~

Use only with Biowelder® S consumables

Sartorius Stedim Switzerland AG
Ringstr. 24a CH-8317
Tagelswangen | Switzerland

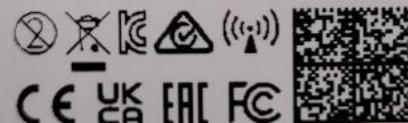


This device complies with
Part 15 of the FCC rules
Developed and
manufactured by
www.reed.ch

EUT

Biowelder® S Cartridge

50 blades for single-use only
Ref-No. BWSBC0010
Lot-No. 1234567.1
Date of mfr. 2023-06-15
Sartorius Stedim Switzerland AG
Ringstr. 24a CH-8317
Tagelswangen | Switzerland



Disposal

1.5 Test Configuration

The RFID module was installed in a Biowelder® S.

1.6 Modes of Operation

The EUT transmitted continuously.



1.7 EUT Modifications Record

The table below details modifications made to the EUT during the test programme.
The modifications incorporated during each test are recorded on the appropriate test pages.

Modification State	Description of Modification still fitted to EUT	Modification Fitted By	Date Modification Fitted
0	As supplied by the customer	Not Applicable	Not Applicable

Table 5

1.8 Test Location

TÜV SÜD Product Service conducted the following tests at our Straubing test laboratory:

Test Name	Name of Engineer(s)
RF Exposure	M. Steindl

Office Address:

Äußere Frühlingstraße 45
94315 Straubing
Germany



2 Test Details

2.1 RF Exposure

2.1.1 Specification Reference

FCC 47 CFR Part 1 I, §1.1310
ISED RSS-102, Clause 4
KDB 447498 D01 V06, section 4.3.1

2.1.2 Equipment under Test and Modification State

RFID Read-Writer; S/N N/A; Modification State 0

2.1.3 Date of Test

2023-11-17

2.1.4 Environmental Conditions

Ambient Temperature	23 °C
Relative Humidity	38 %

2.1.5 Test Method

Estimation is based on a field strength test on the surface of the EUT.



2.1.6 Specification Limits

FCC 47 CFR Part 1 I, § 1.1310(e)(1)

(i) Limits for Occupational / Controlled Exposure

Frequency range (MHz)	E-Field (V/m)	H-field (A/m)	Power density (mW/cm ²)	Averaging time (min)
0.3 – 3.0	614	1.63	*(100)	≤ 6
3.0 – 30	1842 / f	4.89 / f	*(900 / f ²)	< 6
30 - 300	61.4	0.163	1.0	< 6
300 – 1500	---	---	f / 300	< 6
1500 – 100000	---	---	5	< 6

f = frequency in MHz;

* = Plane-wave equivalent power density

(ii) Limits for General Public / Uncontrolled Exposure

Frequency range (MHz)	E-Field (V/m)	H-field (A/m)	Power density (mW/cm ²)	Averaging time (min)
0.3 – 1.34	614	1.63	*(100)	< 30
1.34 – 30	824 / f	2.19 / f	*(180 / f ²)	< 30
30 - 300	27.5	0.073	0.2	< 30
300 – 1500	---	---	f / 1500	< 30
1500 – 100000	---	---	1.0	< 30

f = frequency in MHz;

* = Plane-wave equivalent power density



ISED RSS-102, Clause 4

Table 4: Limits for General Public (Uncontrolled Exposure)

Frequency range (MHz)	E-Field (V/m)	H-field (A/m)	Power density (mW/cm ²)	Averaging time (min)
0.003 – 10	83	90	---	Instantaneous
0.1 – 10	---	0.73 / f	---	6
1.1 – 10	87 / f ^{0.5}	---	---	6
10 – 20	27.46	0.0728	2	6
20 – 48	58.07 / f ^{0.25}	0.1540 / f ^{0.25}	8.944 / f ^{0.5}	6
48 – 300	22.06	0.05852	1.291	6
300 – 6000	3.142 f ^{0.3417}	0.008335 f ^{0.3417}	0.02619 f ^{0.6834}	6
6000 – 15000	61.4	0.163	10	6
15000 – 150000	61.4	0.163	10	616000 / f ^{1.2}
150000 – 300000	0.158 f ^{0.5}	4.21 × 10 ⁻⁴ f ^{0.5}	6.67 × 10 ⁻⁵ f	616000 / f ^{1.2}

Table 6: RF Field Strength Limits for controlled Use Devices (Controlled Environment)

Frequency range (MHz)	E-Field (V/m)	H-field (A/m)	Power density (mW/cm ²)	Averaging time (min)
0.003 – 10	170	180	---	Instantaneous
0.1 – 10	---	1.6 / f	---	6
1.29 – 10	193 / f ^{0.5}	---	---	6
10 – 20	61.4	0.163	10	6
20 – 48	129.8 / f ^{0.25}	0.3444 / f ^{0.25}	44.72 / f ^{0.5}	6
48 – 100	49.33	0.1309	6.455	6
100 – 6000	15.60 f ^{0.25}	0.04138 f ^{0.25}	6.455 f ^{0.5}	6
60000 – 150000	137	0.364	50	6
150000 – 150000	137	0.364	50	616000 / f ^{1.2}
150000 – 300000	0.354 f ^{0.5}	9.40 × 10 ⁻⁴ f ^{0.5}	3.33 × 10 ⁻⁴ f	616000 / f ^{1.2}



2.1.7 Test Results

Tests were performed for general-public-limits.

FCC 47 CFR Part 1 I, § 1.1310(e)(1)(ii)

Frequency: 13.56 MHz
Test distance: 20 cm
Fieldstrength: 0.040 A/m
Fieldstrength limit: 0.162 A/m
Test Result: Pass

ISED RSS-Gen, Clause 3.4

Frequency: 13.56 MHz
Test distance: 20 cm
Fieldstrength: 0.040 A/m
Fieldstrength limit: 0.073 A/m
Test Result: Pass

2.1.8 Test Location and Test Equipment

The test was carried out in EMC test laboratory.

Instrument	Manufacturer	Type No	TE No	Calibration Period (months)	Calibration Due
Electromagnetic radiation meter	Narda	EMR-200	19590	36	2025-12
Magnetic field probe	Narda	Type 12.1	19592	36	2025-12

Table 6

3 Measurement Uncertainty

For a 95% confidence level, the measurement uncertainties for defined systems are:

<i>Radio Interference Emission Testing</i>		
<i>Test Name</i>	<i>kp</i>	<i>Expanded Uncertainty</i>
Conducted Voltage Emission		
9 kHz to 150 kHz (50Ω/50µH AMN)	2	± 3.8 dB
150 kHz to 30 MHz (50Ω/50µH AMN)	2	± 3.4 dB
100 kHz to 200 MHz (50Ω/5µH AMN)	2	± 3.6 dB
Discontinuous Conducted Emission		
9 kHz to 150 kHz (50Ω/50µH AMN)	2	± 3.8 dB
150 kHz to 30 MHz (50Ω/50µH AMN)	2	± 3.4 dB
Conducted Current Emission		
9 kHz to 200 MHz	2	± 3.5 dB
Magnetic Fieldstrength		
9 kHz to 30 MHz (with loop antenna)	2	± 3.9 dB
9 kHz to 30 MHz (large-loop antenna 2 m)	2	± 3.5 dB
Radiated Emission		
30 MHz to 300 MHz	2	± 4.9 dB
300 MHz to 1 GHz	2	± 5.0 dB
1 GHz to 6 GHz	2	± 4.6 dB
Test distance 10 m		
30 MHz to 300 MHz	2	± 4.9 dB
300 MHz to 1 GHz	2	± 4.9 dB
The expanded uncertainty reported according to CISPR16-4-2: 2011 + A1 + A2 + Cor1 is based on a standard uncertainty multiplied by a coverage factor of kp = 2, providing a level of confidence of p = 95.45%		

Table 7 Measurement uncertainty based on CISPR 16-4-2



<i>Radio Interference Emission Testing</i>		
<i>Test Name</i>	<i>kp</i>	<i>Expanded Uncertainty</i>
Occupied Bandwidth	2	± 5 %
Conducted Power		
9 kHz ≤ f < 30 MHz	2	± 1.0 dB
30 MHz ≤ f < 1 GHz	2	± 1.5 dB
1 GHz ≤ f ≤ 40 GHz	2	± 2.5 dB
1 MS/s power sensor (TS8997)	2	± 1.5 dB
Occupied Bandwidth	2	± 5 %
Power Spectral Density	2	± 3.0 dB
Radiated Power		
25 MHz – 6 GHz	1.96	±4.4 dB
1 GHz – 18 GHz	1.96	±4.7 dB
18 GHz – 40 GHz	1.96	±4.9 dB
40 GHz – 325 GHz	1.96	±6.1 dB
Conducted Spurious Emissions	2	± 3.0 dB
Radiated Spurious Emissions	2	± 6.0 dB
Voltage		
DC	2	± 1.0 %
AC	2	± 2.0 %
Time (automatic)	2	± 5 %
Frequency	2	± 10 ⁻⁷

The expanded uncertainty reported according to ETSI TR 100 028:2001 is based on a standard uncertainty multiplied by a coverage factor of $kp = 2$, providing a level of confidence of $p = 95.45\%$

Table 8 Measurement uncertainty based on ETSI TR 100 028

The measurement uncertainty in the laboratory is less than or equal to the maximum measurement uncertainty according to CISPR16-4-2: 2011 + A1 + A2 + Cor1 (U_{CISPR}) and as specified in the test report below. This normative regulation means that the measured value is also the value to be assessed in relation to the limit value.



<i>Test Name</i>	<i>Expanded Uncertainty</i>
Occupied Bandwidth	±5 %
Conducted Power	
9 kHz ≤ f < 30 MHz	±1.0 dB
30 MHz ≤ f < 1 GHz	±1.5 dB
1 GHz ≤ f ≤ 40 GHz	±2.5 dB
1 MS/s power sensor (2.4 / 5 GHz band)	±1.5 dB
Power Spectral Density	±3.0 dB
Radiated Power	
25 MHz – 26.5 GHz	±6.0 dB
26.5 GHz – 66 GHz	±8.0 dB
40 GHz – 325 GHz	±10.0 dB
Conducted Spurious Emissions	±3.0 dB
Radiated Field Strength 9 kHz – 40 GHz	±6.0 dB
Voltage	
DC	± 1.0 %
AC	± 2.0 %
Time (automatic)	± 5 %
Frequency	± 10 ⁻⁷

Table 9 Decision Rule: Maximum allowed measurement uncertainty