# Report on the FCC and IC Testing of the Medela AG

Model: InBra / 101046806

In accordance with FCC 47 CFR,

Part 1, § 1.1307: 2021 and ISED RSS-102

Prepared for: Medela AG

Lättichstrasse 4b

6340 Baar Switzerland

FCC ID: 2ATCR46806 IC: 25040-46806



# COMMERCIAL-IN-CONFIDENCE

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RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Michael Ingerl	2025-08-28	M. SIGN-ID 1069645
Authorised Signatory	Martin Steindl	2025-08-28	Skinell Martin SIGN-ID 1069782

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 reporded testing was carried out on a sample equipment to demonstrate limited compliance with with FCC 47 CFR Part 1, § 1.1307: 2021 and ISED RSS-102.

The sample tested was found to comply with the requirements in the tested parts

Laboratory Accreditation	Laboratory recognition	Industry Canada test site registration
DAkkS Reg. No. D-PL-11321-11-03	Registration No. BNetzA-CAB-16/21-15	3050A-2
DAkkS Rea. No. D-PL-11321-11-04	-	

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Trade Register Munich HRB 85742 VAT ID No. DE129484267 Information pursuant to Section 2(1) DL-InfoV (Germany) at www.tuvsud.com/imprint Managing Directors: Wolfgang Hübl (Sprecher / CEO) Karl Meier Patrick van Welij Phone: +49 (0) 9421 56 82-0 Fax: +49 (0) 9421 56 82-199 www.tuvsud.com TÜV SÜD Product Service GmbH

Äußere Frühlingstraße 45 94315 Straubing Germany



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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	2024-11-05
1	Changed at chapter 2.1.5 the Test Method. (Copy and Paste Failure);	2025-08-28
	Changed at chapter 2.1.6 the fieldstrength from 10m to 3m therefore corrected the power results (Typo);	
	Changed Applicant to Medela AG (Typo)	

**Table 1: Report of Modifications** 

## 1.2 Introduction

Applicant Medela AG Manufacturer Medela AG

Model Number(s) InBra / 101046806

Serial Number(s) DVT-2-066

DVT-2-003

Hardware Version(s) B
Software Version(s) 0.3.2
Number of Samples Tested 2

Test Specification(s) / FCC 47 CFR, Part 1, § 1.1307: 2021 and

Issue / Date ISED RSS-102, Issue 6

Test Plan/Issue/Date ---

Order Number C10002717920

Date of Receipt of EUT 2024-08-26
Start of Test 2024-09-05
Finish of Test 2024-09-27

Name of Engineer(s) Michael Ingerl
Related Document(s) ANSI C63.10:2013

KDB 447498 D04 Interim General RF Exposure Guidance v01



# 1.3 Brief Summary of Results

A brief summary of the tests carried out in accordance with FCC 47 CFR, Part 1, § 1.1307 and ISED RSS-102 is shown below.

Section	Specification Clause	Test Description	Result
2.1	§ 1.1307(b)(3)	RF Exposure Exemption	Pass

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

Ī	Section	Specification Clause	Test Description	Result
Г	2.1	2.5.1	RF Exposure Exemption	Pass

Table 3: Results according to ISED RSS-102



# 1.4 Product Information

# 1.4.1 Technical Description

The Magic InBra breast pump is a personal-use electric breast pump with Fluid Feel Technology™ and 2-Phase Expression Technology™. Mode of operation: continuous. The operating life of the Magic InBra breast pump is 500 hours. The expected operating life of the replaceable washable components is six months.

Frequency Band:	2400.0 MHz – 2483.5 MHz
Supply Voltage:	5 V, battery supplied
Supply Frequency:	DC
	40
	2 MHz
	No
	No
	As per Bluetooth 4.2 Low Energy Standard
	As per Bluetooth 4.2 Low Energy Standard
	Integral Antenna
	2402 MHz: 2.91 dBi 2440 MHz: 1.52 dBi 2480 MHz: 1.67 dBi

# 1.1.1 Test Configuration

Configuration	Description
5 V battery supplied	The EUT is powered via internal battery

# 1.1.2 Mode(s) of Operation

Mode	Description
Continuously transmitting	With DTM mode



# 1.5 EUT Modifications Record

The table below details modifications made to the EUT during the test program.

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 Fit- ted
0	As supplied by the customer SN: DVT-2-066	Not Applicable	Not Applicable

Table 4

Modification State	Description of Modification still fitted to EUT	Modification Fitted By	Date Modification Fit- ted
0	As supplied by the customer (Conducted Sample) SN: DVT-2-003	Not Applicable	Not Applicable

Table 4

# 1.6 Test Location

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

Test Name	Name of Engineer(s)
RF Exposure	Michael Ingerl

#### Office Address:

Äußere Frühlingstraße 45 94315 Straubing Germany



# 2 Test Details

# 2.1 RF Exposure Exemption

# 2.1.1 Specification Reference

47 CFR, Part 1, § 1.1307(b)(3) RSS-102, Issue 6 (2023-12-15)

# 2.1.2 Equipment under Test and Modification State

Magic InBra / 101046806, S/N: DVT-2-066 - Modification State 0 Magic InBra / 101046806 (Conducted Sample), S/N: DVT-2-003 - Modification State 0

#### 2.1.3 Date of Test

2024-09-05 - 2024-09-27



#### Product Service

# 2.1.4 Specification Limits

### 47 CFR, Part 1, § 1.1307(b)(3)

- (i) For single RF sources (i.e. any single fixed RF source, mobile device, or portable device, as defined in paragraph(b)(2) of this section): A single RF source is exempt if:
  - (A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A);
  - (B) Or the available maximum time-averaged power or effective radiate power (ERP), whichever is greater, is less than or equal to the threshold  $P_{th}$  (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHzu (inclusive).  $P_{th}$  is given by

$$P_{th}(\text{mW}) = \begin{cases} ERP_{20\text{cm}} \ (d/20 \ cm)^x, & d \leq 20 \ \text{cm}; \\ ERP_{20\text{cm}}, & 20 \ \text{cm} < d \leq 40 \ \text{cm} \end{cases}$$
 where 
$$x = -\log_{10} \left( \frac{60}{ERP_{20\text{cm}} \sqrt{f}} \right); \ f \ \text{in GHz}$$
 and 
$$ERP_{20\text{cm}} (mW) = \begin{cases} 2040 \ f, & 0.3 \ \text{GHz} \leq f < 1.5 \ \text{GHz} \\ 3060, & 1.5 \ \text{GHz} \leq f \leq 1.5 \ \text{GHz} \end{cases}$$

d = the test separation distance (cm);

(C) Or using the table below and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value described for that frequency. For the exemption in the table to apply, R must be at least  $\lambda/2\pi$  where  $\lambda$  is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of  $\lambda/4$  or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

RF source frequency (MHz)	Threshold ERP (Watts)					
0.3 – 1.34	1920 <i>R</i> <sup>2</sup>					
1.34 – 30	$3450 R^2/f^2$					
30 – 300	$3.83 R^2$					
300 – 1500	0.0128 <i>R</i> <sup>2</sup> <i>f</i> <sup>2</sup>					
1500 – 100000	19.2 <i>R</i> <sup>2</sup>					

- (ii) For multiple RF sources: Multiple RF sources are exempt if:
  - (A) The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of 2 cm between any portion of a radiating structure operating and the nearest portion of any other radiating structure in the same device, except if the sum of multiple sources is less than 1 mW during the time-averaging period, in which case they may be treated as a single source (separation is not required). This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).
  - (B) In case of fixed RF sources operating in the same time-averaging period, or of multiple or portable RF sources within a device in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation:

$$\sum_{i=1}^{a} \frac{P_i}{P_{th,i}} + \sum_{j=1}^{b} \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^{c} \frac{Evaluated_k}{ExposureLimit_k} \le 1$$



Product Service

#### RSS-102, section 2.5.1

SAR evaluation is required if the separation distance between the user and/or bystander and the antenna and/or radiating element of the device is less than or equal to 20 cm, except when the device operates at or below the applicable output power level (adjusted for tune-up tolerance) for the specified separation distance defined in the table below:

	Exemption Limits (mW) at separation distance of									
f (MHz)	≤ 5 mm	10 mm	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm	45 mm	≥ 50 mm
≤ 300	45	116	139	163	189	216	246	280	319	362
450	32	71	87	104	124	147	175	208	248	296
835	21	32	41	54	72	96	129	172	228	298
1900	6	10	18	33	57	92	138	194	257	323
2450	3	7	16	32	56	89	128	170	209	245
3500	2	6	15	29	50	72	94	114	134	158
5800	1	5	13	23	32	41	54	74	102	128

Output power level shall be the higher of the maximum conducted or equivalent isotropically radiated power (e.i.r.p.) source-based, time-averaged output power. For controlled use devices where the 8 W/kg for 1 gram of tissue applies, the exemption limits for route evaluation are multiplied by a factor of 5. For limb-worn devices where the 10 grams value applies, the exemption limits for routine evaluation are multiplied by a factor of 2.5. If the operating frequency of the device is between two frequencies located, linear interpolation shall be applied for the applicable separation distance. For test separation distance less than 5 mm, the exemption limits for a separation distance of 5 mm can be applied to determine if a routine evaluation is required.

For medical implants devices, the exemption limit for routine evaluation is set at 1 mW. The output power of a medical implant device is defined as the higher of the conducted or e.i.r.p. to determine whether the device is exempt from the SAR evaluation.

#### 2.1.5 Test Method

The RF Exposure is based on a SAR exemption calculation for a test separation distance of 0.5 cm.

Note: Power values from the test report TR-713340497-03.



#### 2.1.6 Test Results

# FCC 47 CFR Part §1.1307(b)(3)(i)(A)

Fieldstrength at 3m distance:

Transmit Power in dBm:

Maximum output power:

Minimum test separation distance:

Frequency:

Exemption limit:

Test Result:

288.19 dBµV/m

-7.04 dBm

0.198 mW

0.5 cm

2402 MHz

2.527 mW

#### ISED RSS-Gen, Clause 3.4

Frequency:2402 MHzTest distance:≤ 5 mmCarrier Power (e.i.r.p.):0.198 mWExemption limit:3 mWTest Result:Pass



# 3 Measurement Uncertainty

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

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<sub>CISPR</sub>). This normative regulation means that the measured value is also the value to be assessed in relation to the limit value.

Radio Interference Emission Testing		1
Test Name	kp	Expanded Uncertainty
Conducted Voltage Emission		
9 kHz to 150 kHz (50Ω/50μH AMN)	2	± 3.8 dB
150 kHz to 30 MHz ( $50\Omega/50\mu H$ 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 Field strength		
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 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 5 Measurement uncertainty based on CISPR 16-4-2



Test Name	kp	Expanded Uncertainty
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		
9 kHz ≤ f < 26.5 GHz	2	± 5.6 dB
26.5 GHz ≤ f < 60 GHz	2	± 8.0 dB
60 GHz ≤ f < 325 GHz	2	± 10 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 <sup>-7</sup>

The expanded uncertainty reported according to 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 6 Measurement uncertainty based on ETSI TR 100 028