SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY FOR ELECTROMAGNETIC FIELDS

Based on the measurement results and assessments presented in

TEST REPORT EMV-E 153/21 and **EXPERT OPINION** EMV-E 154/21

it can be stated that the investigated device, Discriminative Metal Detector (DMD)

OPENGATE

manufactured by CEIA S.p.A, Costruzioni Elettroniche Industriali- Automatismi, Zona Industriale Viciomaggio 54; I-52041 Viciomaggio - Arezzo, Italy

fulfils the requirements regarding personal safety in electromagnetic fields and safety of magnetic media according to the following documents:

EC-Rec. 1999/519/EC [a)]	IEEE C95.3-2002 [o)], IEEE C95.3-2021 [p)]
EC-Directive 2013/35/EC [b)]	ACGIH 2020 [q)]
EN 50364:2010 [c)], EN 50364:2018 [d)], and EN 62369-1:2009 [e)]	Safety Code 6 [r)]
EN 62311:2008 [f)], EN IEC 62311:2020 [g)]	Arpansa RPS 3 (2002) [s)], Arpansa RPS S-1 (2021) [t)]
EN 50499:2008 [h)], EN 50499:2019 [i)]	NZS 2772.1:1999 [u)]
ICNIRP Guidelines 1998 [j)] and 2020 [k)]	EN 50527-1:2016 [v)], EN 50527-2-1:2016 [w)], and EN 50527-2-2:2018 [x)]
ICNIRP Guidelines 2010 [l)]	Nbs Special Publication 500.101 [y)]
IEEE C95.1-2019 [m)], IEEE C95.3.1-2010 [n)]	The national archives.org (UK) [z)]

Moreover, under the conditions defined in EN 50364, the ***OPENGATE*** does not emit electric or magnetic field strengths or produce induced voltages above the minimum immunity levels of medical devices, according to the following documents:

EN 45502-2-1:2003 [aa)] (Cardiac pacemakers)	ISO 14708-3:2017 [af)] (Implantable neurostimulators)
EN 45502-2-2:2008 [ab)] (ICDs)	ISO 14708-4:2008 [ag)] (Implantable infusion pumps)
ISO 14117:2019 [ac)] (Card. pacemakers, ICDs, Card. resync. devices)	ISO 14708-5:2020 [ah)] (implantable circulatory support devices)
ISO 14708-1:2014 [ad)] (General minimum requirements)	ISO 14708-6:2019 [ai)] (ICDs)
ISO 14708-2:2019 [ae)] (Cardiac pacemakers)	ISO 14708-7:2019 [aj)] (Cochlea implants)

The ***OPENGATE*** does not emit electric or magnetic field strengths or produce induced voltages that can damage ISO 14708-x-compliant implants.

For details of the listed standards and documents, see page 2 of this document.

Note: According to its technical specification the DUT does not emit ultraviolet-, ionizing- and laser-radiation.

Date: 2022-01-19

Authorized Person:

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1 – Standards / Limits on Human Exposure to Electromagnetic fields:

a) European Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz), 12. July 1999;
b) European Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields), 26. June, 2013;
c) EN 50364:2010. Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 300 GHz, used in Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications;
d) EN 50364:2018. Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 300 GHz, used in Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications;
e) EN 62369-1:2009 Evaluation of human exposure to electromagnetic fields from short range devices (SRDs) in various applications over the frequency range 0 GHz to 300 GHz - Part 1: Fields produced by devices used for electronic article surveillance, radio frequency identification and similar systems;
f) EN IEC 62311:2008. Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz);
g) EN IEC 62311:2020. Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz);
h) EN 50499:2008. Procedure for the assessment of the exposure of workers to electromagnetic fields;
i) EN 50499:2019. Procedure for the assessment of the exposure of workers to electromagnetic fields;
j) ICNIRP Guidelines 1998. Guidelines For Limiting Exposure To Time-Varying Electric, Magnetic, And Electromagnetic Fields (Up To 300 GHz)", International Commission on Non-Ionizing Radiation Protection, Health Physics 74(4):494-522;
k) ICNIRP Guidelines 2020. Guidelines For Limiting Exposure To Electromagnetic Fields (100 kHz To 300 GHz), International Commission on Non-Ionizing Radiation Protection, Health Physics 118(5):483-524;
l) ICNIRP Guidelines 2010. Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz). International Commission on Non-Ionizing Radiation Protection, Health Physics 99(8):18-836 ;
m) IEEE C95.1-2019. IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz;
n) IEEE C95.3.1-2010. Recommended practice for measurements and computations of electric, magnetic, and electromagnetic fields with respect to human exposure to such fields, 0 Hz to 100 kHz;
o) IEEE C95.3-2002. IEEE Recommended Practice for Measurements and Computations of Radio Frequency Electromagnetic Fields With Respect to Human Exposure to Such Fields, 100 kHz-300 GHz;
p) IEEE C95.3-2021. IEEE Recommended Practice for Measurements and Computations of Electric, Magnetic, and Electromagnetic Fields with Respect to Human Exposure to Such Fields, 0 Hz to 300 GHz;
q) ACGIH, 2020. Threshold Limit Value (TLV) for 'Sub-Radiofrequency (30 kHz and below) Magnetic Fields';
r) Safety Code 6 (2015): Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz;
s) ARPANSA RPS 3 (2002): Maximum Exposure Levels to Radiofrequency Fields 3 kHz – 300 GHz;
t) ARPANSA RPS S-1 (2021): Standard for Limiting Exposure to Radiofrequency Fields 100 kHz – 300 GHz;
u) NZS 2772-1:1999: New Zealand Standard Radiofrequency Fields. Part 1: maximum Exposure Levels 3 kHz – 300 GHz;

2 - Standards / Limits on Immunity for carriers of Implantable medical devices:

v) EN 50527-1:2016. Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General;
w) EN 50527-2-1:2016. Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-1: Specific assessment for workers with cardiac pacemakers;
x) EN 50527-2-2:2018. Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-2: Specific assessment for workers with cardioverter defibrillators (ICDs);

3 - Standards / Limits on Immunity for Magnetic media:

y) Nbs Special Publication 500.101 – Care and handling of computer magnetic storage media;
z) Care, Handling and Storage of Removable Media (Section 4) – The national archives.org (UK).

4 - Standards with immunity levels of medical devices

aa) EN 45502-2-1:2003. Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) ISO 14708-2:2012. Implants for surgery – active implantable medical devices – part 2: Cardiac pacemakers;
ab) EN 45502-2-2:2008. Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators);
ac) ISO 14117:2019. Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices;
ad) ISO 14708-1:2014. Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ae) ISO 14708-2:2019. Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers
af) ISO 14708-3:2017. Implants for surgery – active implantable medical devices – part 3: Implantable neurostimulators
ag) ISO 14708-4:2008. Implants for surgery – active implantable medical devices – part 4: Implantable infusion pumps
ah) ISO 14708-5:2020. Implants for surgery – active implantable medical devices – part 5: Circulary support devices
ai) ISO 14708-6:2019. Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
aj) ISO 14708-7:2019. Implants for surgery – active implantable medical devices – part 7: Particular requirements for cochlea implant systems

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