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ACCREDITED TESTING LABORATORY FOR ELECTROMAGNETIC FIELDS

Based on the measurement results and assessments presented in

TEST REPORT EMV-E 82/14 and **EXPERT OPINION** EMV-E 83/14

it can be stated that the investigated device, Walk-Through Metal Detector

HI-PE Plus

manufactured by Costruzioni Elettroniche Industriali Automatismi C.E.I.A. SpA, Zona Industriale 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 C95.3.1-2010 [q)], IEEE C95.3-2002 [r)], IEEE C95.3-2021 [s)]
EC-Directive 2013/35/EC [b)]	ACGIH 2022 [t)]
EN 50364:2010 [c)], EN 50364:2018 [d)], EN 62369-1:2009 [e)]	Safety Code 6 [u)]
EN 62311:2008 [f)], EN IEC 62311:2020 [g)]	Arpansa RPS 3 (2002) [v)], Arpansa RPS S-1 (2021) [w)]
EN 62479:2010 [h)]	NZS 2772-1:1999 [x)]
EN 50499:2008 [i)], EN 50499:2019 [j)]	EN 50527-1:2016 [y)]
ICNIRP Guidelines 1998 [k)] and 2020 [l)]	EN 50527-2-1:2016 [z)], EN 50527-2-2:2018 [aa)], EN 50527-2-3:2021 [ab)]
ICNIRP Guidelines 2010 [m)]	RPB-SC-18 1976 [ac)]
IEEE C95.1-2019 [n)]	Nbs Special Publication 500.101 [ad)]
IEEE C95.1-2005 [o)], IEEE C95.6-2002 [p)]	The national archives.org (UK) [ae)]

Moreover, under the conditions defined in EN 50364, the ***HI-PE Plus*** 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 [af)] (Cardiac pacemakers)	ISO 14708-3:2017 and EN ISO 14708-3:2022 [ak)] (Implantable neurostimulators)
EN 45502-2-2:2008 [ag)] (ICDs)	ISO 14708-4:2008 [al)], ISO 14708-4:2022 and EN ISO 14708-4:2022 [am)] (Implantable infusion pumps)
ISO 14117:2019 [ah)] (Cardiac pacemakers, ICDs, Cardiac resynchronization devices)	ISO 14708-5:2020 and EN ISO 14708-5:2022 [an)] (Implantable circulatory support devices)
ISO 14708-1:2014 [ai)] (General minimum requirements)	ISO 14708-6:2019 and EN ISO 14708-6:2022 [ao)] (ICDs)
ISO 14708-2:2019 and EN ISO 14708-2:2022 [aj)] (Cardiac pacemakers)	ISO 14708-7:2019 and EN ISO 14708-7:2022 [ap)] (Cochlea implants)

The ***HI-PE Plus*** 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.

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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), July 12, 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), June 26, 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 62479:2010+). Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz);
i) EN 50499:2008. Procedure for the assessment of the exposure of workers to electromagnetic fields;
j) EN 50499:2019*). Procedure for the assessment of the exposure of workers to electromagnetic fields;
k) 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;
l) 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;
m) 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;
n) IEEE C95.1-2019*). IEEE Standard for Safety Levels with Respect to Human Exposure to Electric, Magnetic, and Electromagnetic Fields, 0 Hz to 300 GHz;
o) IEEE C95.1-2005. IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz;
p) IEEE C95.6-2002. IEEE Standard for Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0-3 kHz;
q) 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;
r) 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;
s) 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;
t) ACGIH 2022*). Threshold Limit Value (TLV) for 'Sub-Radiofrequency (30 kHz and below) Magnetic Fields';
u) Safety Code 6 2015+). Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz;
v) ARPANSA RPS 3 2002+). Maximum Exposure Levels to Radiofrequency Fields 3 kHz – 300 GHz;
w) ARPANSA RPS S-1 2021+). Standard for Limiting Exposure to Radiofrequency Fields 100 kHz – 300 GHz;
x) 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:

y) EN 50527-1:2016*). Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General;
z) 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;
aa) 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);
ab) EN 50527-2-3:2021+). Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-3: Specific assessment for workers with implantable neurostimulators;
ac) RPB-SC18 1976. Recommended safety procedures for the selection, installation and use of active metal detectors, Health Canada.

3 – Standards / Limits on Immunity for Magnetic media:

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

4 – Standards with immunity levels of medical devices:

af) 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);
ag) 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);
ah) ISO 14117:2019+). Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices;
ai) 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;
aj) ISO 14708-2:2019+), identical with EN ISO 14708-2:2022+). Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers;
ak) ISO 14708-3:2017+), identical with EN ISO 14708-3:2022+). Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators;
al) ISO 14708-4:2008+). Implants for surgery – Active implantable medical devices – Part 4: Implantable infusion pumps;
am) ISO 14708-4:2022+), identical with EN ISO 14708-4:2022+). Implants for surgery – Active implantable medical devices – Part 4: Implantable infusion pumps;
an) ISO 14708-5:2020+), identical with EN ISO 14708-5:2022+). Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices;
ao) ISO 14708-6:2019+), identical with EN ISO 14708-6:2022+). Implants for surgery – Active implantable medical devices – Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators);
ap) ISO 14708-7:2019+), identical with EN ISO 14708-7:2022+). Implants for surgery – Active implantable medical devices – Part 7: Particular requirements for cochlea implant systems.

*) Originally an older version of the standard was used as basis of the Expert Opinion referred to on page 1. However, modifications (if any) of exposure assessment methods and limits introduced by the new version of the standard did not change the overall assessment summarized by the table on page 1.
+) Originally this standard was not considered in the Expert Opinion referred to on page 1. However, based on the test results documented in the Test Report referred to on page 1, compliance of the DUT with the standard, as stated on page 1, can be assumed.
The *Seibersdorf Laboratories GmbH* operates independent accredited testing laboratories and is a 100% subsidiary of the Austrian government majority owned AIT Austrian Institute of Technology.

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