3EC®
international

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2021-MDD/QS-005

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class IIa,

Computer Aided Detection Software: AXIR-CX

manufactured by company

Radisen Co., Ltd.
B-602, Hifield Building 66, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea, 14058

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 01-108-21 (310494) and the Final protocol No. 310494/2021.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if such is required. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on February 17th, 2021

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	17.02.2021	310494	Initially granted certification