



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/121-2019

according to Annex II of Directive 93/42/EEC on Medical Devices as amended.

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices.

MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation.

The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER:

LISTEM Corporation

94, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do (REP. OF KOREA)

DEVICE/S:

Diagnostic X-ray system

MODEL/S:

✓ KAIGEN-40R

✓ KAIGEN-65R

FIRST ISSUE: 06/08/2019

CURRENT ISSUE: 06/08/2019

REVISION Nr.: 00

EXPIRING DATE: 27/05/2024

Dipl.-Ing. Feridoon Sergizzarea

MTIC INTERCERT Certification Body