SZUTEST

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-1808801

Manufacturer: **AIREL**
917 RUE MARCEL PAUL 94500 CHAMPIGNY-SUR-MARNE / FRANCE

Product(s): DENTAL UNITS

Model(s): PACIFIC, K2, PE8

Reference Report No: MM0662-P001-R01, MM0662-P001-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

This EC certificate is valid till 2021-03-28.

Issue Date: 2018-03-29

Rukiye BALKAN
Deputy General Manager

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