

Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directives Medical Device Directive 93/42/EEC

Manufacturer

Name : SMILEXONE EDUCARE PRIVATE LIMITED

Address : FIRST FLOOR, PLOT NO 784 A, JAGAMARA, KHANDAGIRI, KHORDHA, ODISHA, 751030, INDIA

Product : MANUFACTURING DENTAL ALIGNER WITH THE BRAND NAME AESTHETICALIGN AND

AN INDIRECT ORTHODONTIC BRACKET PLACEMENT WITH THE BRAND NAME OF EZ BRACES.

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives Medical Device Directive 93/42/EEC

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.

- 1. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
- 2. The certificate validity is conditioned by positive results or surveillance audits.
- 3. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
- 4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Certificate No. QVA-SEPL-21-293711

Certificate can be verified at www.gaafs.us

Date of Certification

1st Surveillance Due

2nd Surveillance Due

Certificate Expiry (Subject to the company maintaining its system

To the required standard)

29TH September 2021 28TH September 2022

28[™] September 2023

28TH September 2024



Authorized Signatory



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