



Certificate of Compliance

We confirm that the product as mentioned below is Class 1m medical device as confirmed by organization on EC Declaration of Conformity, we also confirm that the technical documentation for the below mentioned product.

Dental Image Processing System and Pre-operative Software - AxisGuide®

Placed in Market by company

ANPA MEDICAL SUPPLIES DMCC

Site: Jumeirah Lake Towers, I-Cluster, Silver Tower, Office # 5G, P.O. Box-346576, Dubai, UAE

Complies with the applicable essential requirements of the European Medical Device Directive 2007/47/EC and the applicable European Product Standard/s as confirmed by the organization on Declaration of Conformity.

The Euro Conformity Assessment has verified with successful results the technical file of the certified product according to relevant parts of the above mentioned harmonized European Medical Device Directive. The product description, documents, assessment procedures and evaluations of the examination are presented in the Technical Construction File (ANPA/TCF/001) kept at manufacturers place.

This Certificate is issued under the following conditions:

1. It applies only to the above referenced set of Products. The manufacturer is obligated to assure that all product of the respective model confirms to the type assessed by this certificate.
2. The Certificate validity is conditioned by the positive results of the surveillance audits.
3. The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed but until the **15 August 2019** at least.
4. After fulfilling the relevant EU legislation requirements, the manufacture shall affix to each product of the above referenced models, CE- marking according to the following example



This Certificate of compliance is for the exclusive use of ECA's client and is provided pursuant to the agreement between ECA and its Client. ECA's responsibility and liability are limited to the terms and conditions of the agreement. ECA assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate of compliance. Only the Client is authorized to permit copying or distribution of this Certificate of compliance. Any use of the ECA name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by ECA. The observations and test/inspection results referenced in this Certificate of compliance are relevant only to the sample tested/inspected.



Signed by : Tech. Manager

Cert. No. : CE/1127/16/02

Issue Date : 16 August 2016

Expiry Date : 15 August 2019