Certificate of Registration

In accordance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

Certificate No.
RUS/2010/02/02

Certificate issue date;
17th January 2019

Certificate expiry date;
31st January 2020

We hereby declare that

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled**

And the CE mark may be applied to the products listed below.

Organisation / Client:

KRK Ltd trading as Anis-Dent Ltd
123060, Berzarina Str
36 Building 2
Moscow
RUSSIA

Products:

Acrylic Teeth Anis

Competent Authority Information:

Class I Medical Device Directive registration is with the UK Medicines and Healthcare Regulatory Agency (MHRA) and the below registration has been issued.

CA011622

Authorised Representative Labelling Information:

EC REP Advena Ltd. Pure Offices, Plato Close, Warwick CV34 6WE UK.

Advena Limited.

Registered office;
Pure Offices, Plato Close, Tachbrook Park
Warwick CV34 6WE. United Kingdom
Registered in England & Wales No. 3517275

☎ +44 1926 800153
Email; info@advenamedical.com

Authorised Signature:

This certificate is subject to the organisation maintaining their documentation in compliance with the regulations stated in this certificate.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

KRK Ltd
Declaration of Conformity for Synthetic Acrylic Teeth

Version	Compiled by	Date	Description
01	Anton Aniskevich	01/02/2010	First issue
02	Shmelev Alexander	13/02/2014	Second issue
03	Shmelev Alexander	07/07/2016	Third issue
04	Shmelev Alexander	20/08/2017	Fourth issue
05	Shmelev Alexander	16/08/2018	Fifth issue

European Communities Council Directive 93/42/EEC Concerning Medical Devices

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Acrylic Teeth Anis
Manufacturer:	413230 Saratovskaya obl. Krasnyi Kut Kuhovarenko 188 007 84560 5 11 06
Variants;	As per ANNEX – product listing
Intended Use:	The intended use of the device is the manufacture of removable dentures
Sterile:	The device we supply is not finished device and with no requirement to be supplied as sterile, the finished device does not need to be sterilised
Measuring Function:	No measurements are made via the device
MDD Directive Classification No:	Class 1
EU Authorised Representative;	Advena Ltd, Pure Offices, Plato Close, Tachbrook Park, Warwick, CV34 6WE, UK
Medical Device Directive Assessment route:	Self certification by Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Signed by Shmelev Alexander **Date 16/08/2018** .....

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under the KRK ltd. name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.