EU DECLARATION OF CONFORMITY

Qamrex Industries

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SRN # ***PK-MF-000028028***

hereby declares that the appointed Authorized EU Representative

IBC-Sweden

14550 Norsborg, Stockholm Sweden eurep@ibcsweden.eu
SRN # ***SE-AR-000001625***

and the EU declaration of conformity for CLASS I (non-sterile, non-active and non-invasive) MEDICAL DEVICES:

Extraction Forceps
Forceps
Bone Rongeur
Dental Elevator
Dental Scissors
Cheek and Lip Retractor
Rubber Dam Punch
Rubber Dam Clamp
Rubber Dam Frame
Scalpel Handle
Needle Holder
Mirror Handle
Mouth Mirror
Dental Explorer
Dental Probe
Dental Filling Instruments
Dental Excavator
Dental Curette
Cement Spatula

Dental Spatula
Dental Lab Carver
Wax Knife
Dental Syringe
Matrix Band Retainer
Crown Remover
Instruments
Articulating Paper
Forceps
Dental Impression Tray
Instruments Tray
Spirit Lamp
Instruments Holder Jar
Dental Carrier
Instruments Box
Dental Gauge
Dental Tweezer
Examination Set
Endodontic Spreader

Dental Scaler
Sterilizing Clamp
Orthodontic Band Pusher
Sinus Lift Elevator
Endodontic Plugger
Dental Bender
Bracket Placing
Instruments
Orthodontic Ligature
Director
Dental Articulator
Dental Chisel
Orthodontic Wire Cutter
Periodontal Knife
Portioner for Ceramic
Material
Dental Plier

Issue Date: 02-09-2022 / EC Certificate: #IBC0220902B

is issued under the sole responsibility of the manufacturer and tends to meet the essential and applicable requirements as per Annex IV under EU MDR 2017/745. Medical Devices attached in Annex A are in conformity with the MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of Official Journal of the European Union, are applied where applicable and presumed to be in conformity with the requirements of ''Risk class I'' of the device in accordance with the rules set out in Annex VIII covered by those standards or parts thereof.

The **CLASS I MEDICAL DEVICES** manufactured are in accordance with applicable requirements of MDR 2017/745 and issued EC Declaration of conformity. The products declared are in compliance to applicable standards and or are harmonized by EU Medical Device Regulation 2017/745. The traceability of the device covered by the EU declaration of conformity are in compliance where appropriate (Quality Management System), as well as its intended purpose.

We also declare; documents will be presented upon request, the indicated therein, **Qamrex Industries** will provide that technical documentation in its entirety and or in summary thereof.
The product manufactured is Medical Devices (Non-Sterilized) is in class I as low risk product, lower risk products in line with Annex VIII; The product referred are developed with due care in lieu of technical documentation referred to in Annexes II and III.

To keep the technical documentation, the EU declaration of conformity and relevant certificates, including any amendments and supplements, issued in accordance with Article 56, available for a period of at least 05 years after the last device covered by the EU declaration of conformity has been placed on the market.

For and on behalf of Qamrex Industries

QAMREX
INDUSTRIES
Proprietor