EU – Declaration of Conformity

We, **PEKA Stanz- und Klebetechnik GmbH & Co. KG** - Am Forst 30 - D-74889 Sinsheim, represented by Alexander Nägele, CEO, declare under our sole responsibility that the medical devices of the group

peka-med medical Facemasks

Basic UDI-DI: 426073619 01354013014019 2Z

complies with the relevant provisions of Regulation (EU) 2017/745 (MDR) on medical devices and, where applicable, other relevant Union legislation

The product group includes the following medical devices			
Commercial name	**Article No.**	**Commercial name**	**Article No.**
peka-med MNS Premium	MEDMNSP50110		

Intended use of the product group: Type IIR medical face masks for third-party protection of the wearer's counterpart (e.g.patient) from exposure to potentially infectious aerosol droplets.

According to Annex VIII, Rule 1 MDR, all devices in the product group are class 1 medical devices and the applicable essential safety and performance requirements according to Annex I MDR are fulfilled. A conformity assessment procedure according to Annex II & III MDR has been carried out.

Applicable harmonized standards, national standards, or other regulatory documents:

EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 14971:2019 – Medical devices – Application of risk management to medical devices

EN 14683:2019 – Medical face masks– Requirements and test methods

This EU Declaration of Conformity is valid until **06th of May 2022**

Sinsheim, the 06th of May 2021

Alexander Nägele

CEO

Manufacturers SRN: requested