

AL-88350

Documentation Review



No. 4N200323.DKHD001

Holder:

Dongguan Kangpai Health Technology Co., Ltd.

Room 101, No. 38, Huanghe Road,
Fenghuanggang, Tangxia Town, Dongguan,
Guangdong

Review goal:

Verification of the presence of Technical
Documentation compatible with the
Medical Devices **Directive** 93/42/EEC
Annex VII

Product:

N95MASK(FP2)(Not Sterile)

Model(s):

KPK-001, KPK-002

Classification:

Class (Not Sterile)
(accordingly to the **Manufacturer's declaration**)

Review output:

This document has been issued on a **voluntary** basis
and upon request of the **manufacturer**. It is **our opinion**
that the Technical **Documentation** shared with us by
the **manufacturer** is **compatible** with the European
Standard for **Medical Devices**.

The **manufacturer** is **responsible** for the CE Marking
process, and not exempted to carry out all necessary
compliance activities. This document has been issued
on the basis of the **regulation** on ECM Voluntary **Mark**
for the **certification** of products. RG01_ECM rev.3
available at: www.entecerma.it

Date of issue 23 March 2020

Approver

ECM Service Director

Luca Bedonni



Expiry date 22 March 2025

Technical Expert

Amanda Payne

