

EC Declaration of Conformity

Manufacturer: Hellenic Medical Supplies G.P.

Address: 6th km Xanthi - Lefkopetra – 67100 Xanthi – Greece

SRN (Single Registration Number): Currently not available (EUDAMED)

Basic UDI-DI: 5200040294MASKSURGICALS8

Name of the Device(s): Surgical face masks 3 ply ciel type II 50 pcs
Surgical face masks 3 ply ciel type II 20 pcs
Surgical face masks 3 ply green type II 50 pcs
Surgical face masks 3 ply green type II 20 pcs
Surgical face masks 3 ply black type II 50 pcs
Surgical face masks 3 ply black type II 20 pcs
Surgical face masks 3 ply pink type II 50 pcs
Surgical face masks 3 ply pink type II 20 pcs
Surgical face masks 3 ply purple type II 50 pcs
Surgical face masks 3 ply purple type II 20 pcs

Product code: XXXXXXXX

GMDN: 35177, Surgical face mask, single use

CND: T020601, Standard surgical face masks

Classification: Class I

Conformity assessment route according the Regulation MDR 2017/745: EC conformity declaration according to Annex IV after drawing up the technical documentation set out in Annexes II and III.

Hellenic Medical Supplies G.P. declares under its sole responsibility that, for the medical device(s) specified above, meets the provision of the Regulation (EU) MDR 2017/745 for medical devices, has developed and implements a Quality Management System and has drawn up the Technical Documentation.

Product related Standard: EN 14683:2019+AC:2019.

Signature:

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Name, General Manager

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Place and date of issue

Xanthi, 22/07/2020