

GCMEDICA ENTERPRISE LTD;(WUXI)

Loujin Industrial Park, Shuofang, Wuxi, Jiangsu Province, P.R.CHINA

EU DECLARATION OF CONFORMITY

No.: GC4048H01/GC4048H02-20210217

- (1) PPE face shield designed to be safe the user for eye and face protector, GCMEDICA model: GC4048H01/GC4048H02
- (2) Manufacturer: **GCMEDICA ENTERPRISE LTD;(WUXI)** Loujin Industrial Park, Shuofang, Wuxi, Jiangsu Province, P.R.CHINA
- (3) The sole responsibility for issuing this declaration of conformity is with manufacturer: **GCMEDICA ENTERPRISE LTD;(WUXI)**
- (4) Subject of the declaration: GCMEDICA GC4048H01/GC4048H02, these products are intended for protection against liquid splashes, as encountered in medical activities, etc. Which are likely to damage the eye or impair vision.
- (5) The face shield mentioned under (4) meet the basic safety and health requirements of ANNEX2 of the PPE regulation (EU) 2016/425 and directive 2001/95/EC on General Product safety.
- (6) Harmonized standards used: EN166:2001
- (7) The notified body ECS GmbH Huettfeldstrasse 50, 73430 Aalen, Germany, identification number 1883 has carried out the EU type examination (module B) test report number 1019-ECS-21/MR 10191-ECS-21 and EU type Examination Certificate C3246.1GCMEDICA were issued on February.17.2021.
- (8) The PPE face shield has been assigned to Category II according to ANNEX I of the PPE regulation (EU) 2016/425.

Signed for and on behalf of:

GCMEDICA ENTERPRISE LTD;(WUXI)

无锡市九龙医疗器械有限公司
GCMEDICA ENTERPRISE
LTD.(WUXI)



21.2.17.

Mr. Adam Jiang

WUXI on February. 17.2021



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Appendix 1

Size	GCMEDICA Product Name	GCMEDICA Model	Mölnlycke Product Name	Mölnlycke Product code
330x170mm	Face Shield	GC4048H01	Face Shield	1711
330x220mm	Face Shield	GC4048H02	Face Shield	1710