

## NOTIS

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## Notify medical devices and IVDs

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### Product

Status	BEV - Notification confirmed
Brand name	Blozek medical
Alternative brand name	
Group name	
Article number(s)	BNCP-402
Model(s)	COVID-19 IgG/IgM rapid test cassette
Class	Other in-vitro medical devices
Notified body	
Classification rule	
Type	CE-markering
Category/Categories	06 - In vitro diagnostic devices
GMDN Code	
Other nomenclature	EDMA: 15 70 90 90 00
Brief description (in English)	A rapid test for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimens.
Brief description (in Dutch)	Een sneltest voor de kwalitatieve detectie van IgG of IgM antilichamen van COVID-19 in bloed, serum en plasma
New product	Yes
CE mark valid through	
Name of manufacturer	Inzek International Trading

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