

EU DECLARATION OF CONFORMITY – MDR

1)This declaration of conformity is issued under the sole responsibility of the importer:

BTW/TVA BE 0429 166 206

VANZEEBROECK NV - SA - HEVA G Demeurslaan 73 B -1654 Huizingen

for

2) the products mentionned below: - Nitrile disposable gloves 3.5 gr powderfree - HEVA

	BLUE	Black	White
Small	460160	460269	460369
Medium	460177	460276	460376
Large	460184	460283	460382
X- Large	460191	460290	460399
XX Large	460108		

Boxes under this regulation will always have the notifictation MD for Medical Device



- 3)The object of the declaration described in point 2 is in conformity with the relevant Union harmonisation legislation: Medical Device Regulation (EU) 2017/745 - Class I (Annex VIII)
- 4) The product is conform to the relevant harmonised standards used and referred to,

	EN 455-1 :2020	
Standards/ Technical	EN 455-2: 2015 +A1:2011	
Specifications applied	EN 455-3: 2015	
	EN 455-4 :2009	

5) HEVA declares that the product, as mentionned above, is confrom the applicable legislation based on the different testreports of SGS (EN 455-1,2,3) and the accelerated aging test (EN 455 – 4) done by the ISO certified labo of the factory itself.







H. Vanzeebroeck NV-SA

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De BTW/TVA BE 0429 166 206 De RPR Brussel



Date of issue	01/03/2023
	Geert Van Zeebroeck, owner
Name, function	The



