From: Sarah Palmer <spalmer@maxtec.com>
Date: Tue, 13 Feb 2024 at 08:45
Subject: RE: EyeMax2 IFU in editable/Word format.
To: steve.nixon@viamed.co.uk <steve.nixon@viamed.co.uk>

Good morning Steve

I´ve been discussing this with our QA dept and they informed that we can provide this as the IFU is a controlled document. Below is an overview from our QA dept regarding the translation requirements for Eyemax IFU under MDR:

LEGEND	
	Language Present in IFU
X	Shipped Into
	Maxtec Default Language
	Needed to Close Gap
	Translation Required
	English accepted as professional use language

Country	For Professional Users	Official Language	EyeMax2
Austria	German, English	German	X
Belgium	English, French, Dutch, German *conditions apply	Dutch, French, German	X
Bulgaria	Bulgarian	Bulgarian	X
Switzerland	German, French, Italian	German, French, Italian	X
Cyprus	English, Greek	Greek	
Czech	Czech	Czech	
Germany	English, German *conditions apply	German	X
Denmark	Danish*exemption possible	Danish	X
Estonia	English, Estonian *conditions apply	Estonian	X
Spain		Spanish	X
Finland	Finnish, Swedish *conditions apply	Finnish, Swedish	X
France	French	French	X
Greece	Greek *conditions possible	Greek	
Croatia	English, Croatian	Croatian	

Hungary	Hugarian	Hungarian	
Ireland	English, Irish	Irish, English	
Iceland		North German, Icelandic	
Italy	Italian	Italian	X
Latvia	Latvian	Latvian	
Malta	English, Maltese	Maltese, English	
Netherlands	English, Dutch *conditions apply	Dutch	X
Norway		Norwegian, Sami	
Poland	Polish or English, conditions apply	Polish	X
Portugal	Portuguese	Portuguese	
Romania	Romanian or English, conditions apply	Romanian	X
Sweden	Swedish, exemption possible*	Swedish	X
Slovenia	Slovene, exemption possible*	Slovenian	X
Lithuania	Lithuanian	Lithuanian	
Luxembourg	English, French, German, Luxembourg	French, German	
Slovakia	Slovak	Slovak	

For Romania, English IFU is accepted so is there a reason you can go ahead with this?

Many thanks!

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