

Application for exemption from the conformity assessment procedure (CE-marking) of a medical device

An exemption from the conformity assessment procedure must be in the interest of public health or patient safety or health. Therefore, the application must include a statement from the user of the device explaining why this device is necessary to protect public health or patient safety or health.

This form is to be filled in by the user/clinician	
Name of the device	Name of the health institution that will use the device
Name of the user/clinician	The user/clinician's professional title
Phone number	Email address
Are there alternative CE-marked devices or procedures available on the market?	
Explain why any available CE-marked devices or alternative procedures are not a suitable alternative for the patient(s). If financial considerations prevent the use of alternative devices, provide a timeline for when alternative devices can be acquired and used.	
Indicate what measures have been taken to find alternative CE-marked devices or procedures.	

Justification based on a specific need of one particular patient or targeted patient group.

Describe the possible consequences if the patient(s) cannot access the device(s)

Do you have any information about the need for the device in other health institutions in Norway? If yes, which ones?

Indicate the urgency of the application.

Date, name and title

Signature