

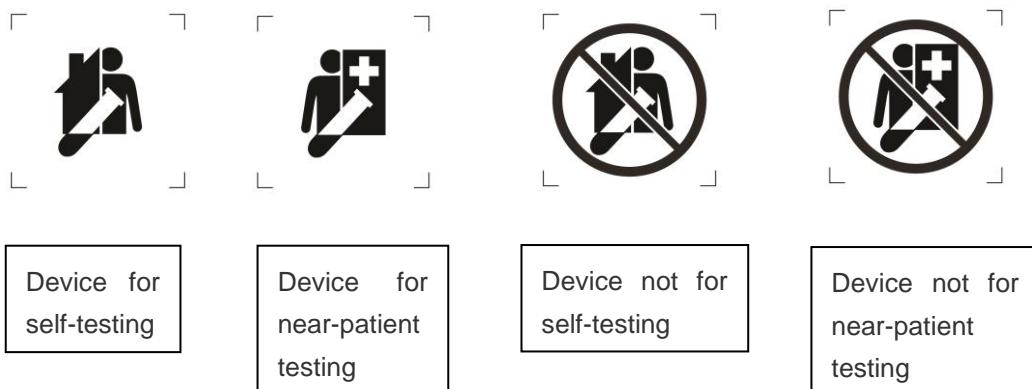
Symbols for self-testing and near-patient testing under the IVD Regulation 2017/746/EU

13 December 2018

The IVD Regulation 2017/746/EU ('IVD Regulation') has new requirements which ask for information regarding self-testing and near-patient testing to be added to the labels of certain devices. With this Regulatory Update, MedTech Europe would like to communicate about the four new symbols which it supports for self-testing and near-patient testing.

In Europe, the necessity to translate the information provided on the labels in several languages creates the need for manufacturers to use symbols. The use of symbols on the label as an alternative to written language is permitted in the IVD Regulation (see Annex I, Chapter III, 20.1h).

IVD Regulation requires that the device intended for self-testing or near-patient testing must indicate this fact on the label.¹ Another requirement is that rapid tests which are **not** intended for self-testing or near-patient testing should bear an explicit exclusion of this fact on their label.² For this reason, **the following four new symbols are supported by MedTech Europe in order to convey this information when required, on the label:**



¹ IVD Regulation Annex I, 20.2

The label shall bear all of the following particulars: [...]

(q) If the device is intended for self-testing or near-patient testing, an indication of that fact;

² IVD Regulation Annex I, 20.2

The label shall bear all of the following particulars: [...]

(r) Where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;

It should be noted that **the negation symbols are only required to be used in the context of rapid tests, when appropriate.** While there is no EU definition of ‘rapid test’ available today, MedTech Europe’s Labelling (IVD) Working Group is working on developing a definition of ‘rapid test’ as part of future MedTech Europe Guidance on changes to Labelling and Instructions for Use under the IVD Regulation.

To select these four symbols, MedTech Europe went through a vigorous process of discussion, design and selection. The symbols should be recognizable even at 5 mm, which means that they should ‘work’ should the manufacturer choose to add them at this size to the device label. Translations of the symbols are provided in the annex to this document.

It is MedTech Europe’s intention both to communicate about these symbols through industry guidance and to support user awareness of these symbols. A campaign to build up user awareness of the symbols is foreseen towards the end of the transition period. MedTech Europe eventually plans to support inclusion of these symbols in the symbols standard ISO 15223 if possible. Given that the inclusion of these symbols into the harmonised standard is not expected to happen for some years, it will be necessary to describe the use of these symbols in the accompanying Instructions for Use.

Conclusions

By 26 May 2022, IVD devices will need to transition to the new IVD Regulation. Devices intended for self-testing, devices intended for near-patient testing and certain rapid tests will be required to include new information on the label. Four new symbols are supported by MedTech Europe to communicate this information, when required, on the label. In taking the same approach when using these symbols, the IVD industry will support the use of symbols and increase user awareness of their meaning across our markets. By communicating about these symbols today, MedTech Europe hopes that companies will be able to take the symbols into account when preparing their labelling for compliance to the new requirements of the IVD Regulation.

For further information on the content of this Regulatory Update, please contact:

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Annex – Symbols Template

Note on using the template provided below:

- If some of the symbols or languages are not needed for your particular needs, you can drop all or some of the symbols or languages from the list but **MedTech Europe asks you to keep always the same order** as shown in the below the listing. Using always the same order by the manufacturer will speed up user recognition and acceptance of the symbols and their meaning.
- Please make sure you **always use the same explanations as given in the template** (to avoid any confusion amongst users).



EN	Device for self-testing
DE	Produkt zur Eigenanwendung
FR	Dispositif d'autodiagnostic
BG	Изделие за самотестване
CS	Prostředek pro sebetestování
DA	Udstyr til selvtestning
EL	Τεχνολογικό προϊόν για αυτοδιάγνωση
ES	Producto para autodiagnóstico
ET	Enesetestimise meditsiiniseade
FI	Itse suoritettavaan testaukseen tarkoitettu laite
GA	Feiste le haghaidh féintástála
HR	Proizvod za samotestiranje
HU	Önenlőrzésre szolgáló eszköz
IT	Dispositivo per test autodiagnostico
LT	Savikontrolės priemonė
LV	Paštestēšanas ierīce
MT	Apparat għall-awttestjar
NL	Hulpmiddel voor zelftesten
NO	Utstyr til selvtesting



EN	Device for near-patient testing
DE	Produkt für patientennahe Tests
FR	Dispositif de diagnostic près du patient
BG	Изделие за тестване на място
CS	Prostředek pro vyšetření v blízkosti pacienta nebo přímo u pacienta
DA	Udstyr til patientnær testning
EL	Τεχνολογικό προϊόν για διαγνωστικές εξετάσεις κοντά στον ασθενή
ES	Prueba diagnóstica en el lugar de asistencia al paciente
ET	Seade patsientide vahetus läheduses testimiseks
FI	Vieritestauslaite
GA	Feiste le haghaidh tástáil neas-othair
HR	Proizvod za testiranje u blizini pacijenta
HU	Betegközeli laboratórium diagnosztikára használt eszköz
IT	Dispositivo per analisi decentrate (near-patient testing)
LT	Tyrimų prie paciento lovos (TpPL) priemonė
LV	Pacienttuvas testēšanas ierīce
MT	Apparat għall-ittestjar qrib il-pazjent
NL	Hulpmiddel voor patiëntnabije tests (hulpmiddel voor near-patient testing)
NO	Utstyr til pasientnær testing

PL	Wyrób do samokontroli
PT	Dispositivo de autodiagnóstico
RO	Dispozitiv de autotestare
RU	Изделие для самотестирования
SK	Pomôcka na samotestovanie
SL	Pripomoček za samotestiranje
SR	Proizvod za samotestiranje
SV	Produkt för självtestning
TR	Hastanın kendi kendini test etmesi amaçlı cihaz

PL	Wyrób do badań przyłożkowych
PT	Dispositivo para diagnóstico junto do doente (near-patient testing)
RO	Dispozitiv pentru testare în proximitatea pacientului
RU	Изделие для внелабораторного тестирования
SK	Pomôcka na delokalizovanú diagnostiku
SL	Pripomoček za testiranje ob pacientu
SR	Proizvod za testiranje u blizini pacijenta
SV	Produkt för patientnära testning
TR	Hasta başında test amaçlı cihaz



EN	Device not for self-testing
DE	Produkt nicht zur Eigenanwendung
FR	Dispositif non destiné à l'autodiagnostic
BG	Изделието не е предназначено за самотестване
CS	Prostředek není určen pro sebetestování
DA	Udstyr ikke beregnet til selvtestning
EL	Συσκευή ακατάλληλη για αυτοδιάγνωση
ES	No destinado para el autodiagnóstico
ET	Seade ei ole enesetestimiseks
FI	Laite, jota ei ole tarkoitettu itse suoritettavaan testaukseen
HR	Nije namijenjeno za samotestiranje
HU	Nem önellenőrzésre szolgáló eszköz



EN	Device not for near-patient testing
DE	Produkt nicht für patientennahe Tests
FR	Dispositif non destiné au diagnostic près du patient
BG	Изделието не е предназначено за тестване на място
CS	Prostředek není určen pro vyšetření v blízkosti pacienta nebo přímo u pacienta
DA	Udstyr ikke beregnet til patientnær testning
EL	Συσκευή ακατάλληλη για διαγνωστικές εξετάσεις κοντά στον ασθενή
ES	No destinada para diagnóstico en el lugar de asistencia al paciente
E	Seade ei ole patsientide vahetus läheduses testimiseks
T	Laite, jota ei ole tarkoitettu vieritestaukseen
HR	Nije namijenjeno za testiranje u blizini pacijenta
HU	Nem betegközeli laboratóriumi diagnosztikára szolgáló eszköz

IT	Dispositivo non destinato a test autodiagnostico
LT	Prietais as neskirtas savikontrolei
LV	Ierīce nav paredzēta paštestēšanai
NL	Geen hulpmiddel voor zelftesten
NO	Utstyret er ikke til selvtesting
PL	Wyrób nieprzeznaczony do samokontroli
PT	O dispositivo não se destina a autodiagnóstico
RO	Nu este destinat a fi utilizat pentru autotestare
RU	Изделие не для самотестирования
SK	Pomôcka nie je určená na samotestovanie
SL	Pripomoček ni za samotestiranje
SR	Proizvod nije za samotestiranje
SV	Produkt ej avsedd för självtestning
TR	Cihaz hastanın kendi kendini test etmesi amaçlı değildir

IT	Dispositivo non destinato ad analisi decentrate (near-patient testing)
LT	Prietais as neskirtas tyrimams prie paciento lovos (TpPL)
LV	Ierīce nav paredzēta pacientuvai testēšanai
NL	Geen hulpmiddel voor patiëntnabije testen
NO	Utstyret er ikke til pasientnær testing
PL	Wyrób nieprzeznaczony do badań przyłożkowych
PT	O dispositivo não se destina a diagnóstico junto do doente (near-patient testing)
RO	Nu este destinat a fi utilizat pentru testare în proximitatea pacientului
RU	Изделие не для внелабораторного тестирования
SK	Pomôcka nie je určená na delokalizovanú diagnostiku
SL	Pripomoček ni za testiranje ob pacientu
SR	Proizvod nije za testiranje u blizini pacijenta
SV	Produkt ej avsedd för patientnära testning
TR	Cihaz hasta başında test amaçlı değildir