



OFFERYNNAU STATUDOL
CYMRU

WELSH STATUTORY
INSTRUMENTS

2020 Rhif 1489 (Cy. 318)

2020 No. 1489 (W. 318)

**IECHYD Y CYHOEDD,
CYMRU**

PUBLIC HEALTH, WALES

**Rheoliadau Cyfarpar Diogelu
Personol (Trefniadau Dros Dro)
(Coronafeirws) (Cymru) 2020**

**The Personal Protective Equipment
(Temporary Arrangements)
(Coronavirus) (Wales) Regulations
2020**

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

Mae'r Rheoliadau hyn wedi eu gwneud o dan adran 45C, 45F(2) a 45(P) o Ddeddf Iechyd y Cyhoedd (Rheoli Clefydau) 1984 i weithredu trefniadau dros dro i hwyluso cynhyrchu a chyflenwi cyfarpar diogelu personol (PPE) yn ystod yr argyfwng Covid-19. Mae'r trefniadau hyn yn debyg i'r cynigion yn Argymhelliad y Comisiwn Ewropeaidd 2020/403 dyddiedig 13 Mawrth 2020 ar weithdrefnau asesu cydymffurfiaeth a gwyliadwraeth y farchnad yng nghyd-destun bygythiad COVID-19 (OJ L 79I, 16.3.20 t. 1-5), ond mae'r trefniadau yn y Rheoliadau hyn yn benodol i Gymru ac ni chaniateir dibynnu arnynt oni bai bod yr Awdurdod Gweithredol Iechyd a Diogelwch wedi eu hawdurdodi erbyn dyddiad penodedig ac maent yn dod i rym ar ddiwrnod cwblhau'r cyfnod gweithredu.

Mae rheoliad 2 yn caniatáu i PPE gael ei roi ar y farchnad tra ei fod yn destun gweithdrefnau asesu cydymffurfiaeth ond cyn i'r gweithdrefnau hyn gael eu cwblhau a chyn i unrhyw nod cydymffurfiaeth gael ei osod arno. Mae rheoliad 3 yn caniatáu i PPE gael ei gaffael heb fod yn destun gweithdrefnau asesu cydymffurfiaeth a heb fod nod cydymffurfiaeth wedi ei osod arno, ond ni ddylai'r PPE hwnnw fod ar gael i neb ond gweithwyr gofal iechyd a gweithwyr rheng flaen yn unig. Yn y ddau achos, rhaid i'r PPE fod wedi ei asesu gan yr Awdurdod Gweithredol Iechyd a Diogelwch a rhaid i'r awdurdod hwnnw fod wedi canfod bod y PPE yn cydymffurfio â'r gofynion iechyd a diogelwch hanfodol yn Atodiad II i Reoliad

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under section 45C, 45F(2) and 45(P) of the Public Health (Control of Disease) Act 1984 implementing temporary arrangements to facilitate the production and supply of PPE during the Covid-19 crisis. These arrangements are similar to the proposals in the European Commission's Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat ((OJ L 79I, 16.3.20 p. 1-5), but the arrangements in these Regulations are specific to Wales and may only be relied on if the HSE has authorised them by a specified date and come into force on IP completion day.

Regulation 2 permits PPE to be placed on the market while it is undergoing conformity assessment procedures but before these have been completed and any conformity marking has been affixed. Regulation 3 permits PPE to be procured without undergoing conformity assessment procedures and conformity marking being affixed but this must only be made available to healthcare and frontline workers. In both cases, the PPE must have been assessed by the HSE and found to be compliant with the essential health and safety requirements in Annex II of Regulation 2016/425/EU of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive

2016/425/EU Senedd Ewrop a'r Cyngor dyddiedig 9 Mawrth 2016 ar gyfarpar diogelu personol ac sy'n diddymu Cyfarwyddeb y Cyngor 89/686/EEC (fel y'i diwygiwyd ac fel y'i dargedwir yng nghyfraith y DU). Pan fo'r amodau wedi eu bodloni, caiff y rhwymedigaethau yn Rheoliad 2016/425 eu trin fel pe baent wedi eu bodloni at ddibenion Rheoliadau Cyfarpar Diogelu Personol (Gorfodi) 2018 (O.S. 2018/390) ac mewn cysylltiad â PPE ar gyfer gweithwyr gofal iechyd a gweithwyr rheng flaen eraill, ni fydd awdurdod gwyliadwraeth y farchnad yn ei gwneud yn ofynnol i ddod â'r peidio â chydymffurfio i ben. Nid yw hyn yn gymwys ond mewn achosion pan na fo'r weithdrefn asesu cydymffurfiaeth wedi ei chwblhau a phan na fo'r nod cydymffurfiaeth wedi ei osod ar y PPE oherwydd dibynnu ar reoliadau 2 neu 3 o'r Rheoliadau hyn.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ni luniwyd asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

89/686/EEC (as amended and retained in UK law). Where the conditions are met, the obligations in Regulation 2016/425 will be treated as satisfied for the purposes of the Personal Protective Equipment (Enforcement) Regulations 2018 (S.I. 2018/390) and in respect of PPE for healthcare workers and other frontline workers, the market surveillance authority will not require the non-compliance to be brought to an end. This is solely in cases where the conformity assessment procedure has not been completed and the conformity mark has not been affixed due to reliance on regulation 2 or 3 of these Regulations.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has not been prepared as to the likely cost and benefit of complying with these Regulations.

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PUBLIC HEALTH, WALES

**Rheoliadau Cyfarpar Diogelu
Personol (Trefniadau Dros Dro)
(Coronafeirws) (Cymru) 2020**

**The Personal Protective Equipment
(Temporary Arrangements)
(Coronavirus) (Wales) Regulations
2020**

Gwnaed 9 Rhagfyr 2020

Made 9 December 2020

Gosodwyd gerbron *Senedd*
Cymru 10 Rhagfyr 2020

Laid before Senedd Cymru 10 December 2020

Yn dod i rym yn unol â rheoliad 1(1)

*Coming into force in accordance with
regulation 1(1)*

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddir gan adran 45C, 45F(2) a 45P(2) o Ddeddf Iechyd y Cyhoedd (Rheoli Clefydau) 1984(1).

The Welsh Ministers make the following regulations in exercise of the powers conferred by section 45C, 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984(1).

Mae Gweinidogion Cymru yn ystyried bod y cyfyngiadau a'r gofynion a osodir gan y Rheoliadau hyn yn gymesur â'r hyn y maent yn ceisio ei gyflawni, sef ymateb iechyd y cyhoedd i'r bygythiad i iechyd y cyhoedd a berir gan fynychder a lledaeniad coronafeirws syndrom anadlol aciwt difrifol 2 (SARS-CoV-2) yng Nghymru.

The Welsh Ministers consider that the restrictions and requirements imposed by these Regulations are proportionate to what they seek to achieve, which is a public health response to the threat to public health posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wales.

Mae Gweinidogion Cymru yn datgan, yn unol ag adran 45Q(3), eu bod o'r farn nad yw'r Rheoliadau hyn yn cynnwys unrhyw ddarpariaeth a wneir yn rhinwedd adran 45C(3)(c) o'r Ddeddf honno sy'n gosod, neu'n galluogi gosod, cyfyngiad arbennig neu ofyniad arbennig, neu unrhyw gyfyngiad neu ofyniad arall sy'n cael, neu a fyddai'n cael, effaith sylweddol ar hawliau person.

The Welsh Ministers declare, in accordance with section 45Q(3), that they are of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of that Act which imposes or enables the imposition of a special restriction or requirement, or any other restriction or requirement which has or would have a significant effect on a person's rights.

(1) 1984 p. 22. Mewnosodwyd adran 45C gan adran 129 o Ddeddf Iechyd a Gofal Cymdeithasol 2008 (p. 14). Mae'r swyddogaeth o dan yr adran hon wedi ei rhoi i "the appropriate Minister" ("y Gweinidog priodol"). O dan adran 45T(6) o Ddeddf 1984, y Gweinidog priodol, o ran Cymru, yw Gweinidogion Cymru.

(1) 1984 c. 22 Section 45C was inserted by section 129 of the Health and Social Care Act 2008 (c. 14). The function under this section is conferred on "the appropriate Minister". Under section 45T(6) of the 1984 Act the appropriate Minister, in respect of Wales, is the Welsh Ministers.

Enwi, cychwyn, cymhwyso a dehongli

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Cyfarpar Diogelu Personol (Trefniadau Dros Dro) (Coronafeirws) (Cymru) 2020 ac maent yn dod i rym ar ddiwrnod cwblhau'r cyfnod gweithredu.

(2) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

(3) Yn y Rheoliadau hyn—

(a) ystyr “y Rheoliad PPE” (“*the PPE Regulation*”) yw Rheoliad (EU) 2016/425 Senedd Ewrop a'r Cyngor dyddiedig 9 Mawrth 2016 ar gyfarpar diogelu personol ac sy'n diddymu Cyfarwyddeb y Cyngor 89/686/EEC(1);

(b) mae i ymadroddion Cymraeg yn y Rheoliadau hyn sy'n cyfateb i ymadroddion Saesneg sy'n ymddangos yn y Rheoliad PPE yr un ystyr ag y sydd iddynt yn y Rheoliad PPE;

(c) ystyr “Rheoliadau 2018” (“*the 2018 Regulations*”) yw Rheoliadau Cyfarpar Diogelu Personol (Gorfodi) 2018(2);

(4) Yn y Rheoliadau hyn—

ystyr “yr Awdurdod Gweithredol Iechyd a Diogelwch” (“*the HSE*”) yw'r Awdurdod Gweithredol Iechyd a Diogelwch(3);

ystyr “clefyd y coronafeirws” (“*coronavirus disease*”) yw COVID-19 (sef dynodiad swyddogol y clefyd a achosir gan y coronafeirws);

ystyr “corff a hysbyswyd” (“*notified body*”) yw corff asesu cydymffurfiaeth nad yw'n gorff cymeradwy, yr aseiniwyd rhif adnabod iddo o dan Erthygl 29 o Reoliad (EU) 2016/425 (fel y mae'n cael effaith yng nghyfraith yr UE).

ystyr “coronafeirws” (“*coronavirus*”) yw syndrom anadlol aciwt difrifol 2 (SARS-CoV-2);

ystyr “GIDH” (“*EHSR*”) yw'r gofynion iechyd a diogelwch hanfodol sy'n gymwys i PPE Covid fel y nodir yn Atodiad 2 i'r Rheoliad PPE;

(1) Mae'r Rheoliad PPE wedi ei gorffori yng nghyfraith ddomestig gan adran 3(1) o Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 (p. 16) ac wedi ei ddiwygio'n rhagolygol gydag effaith o ddiwrnod cwblhau'r cyfnod gweithredu gan reoliad 38 o Reoliadau Diogelwch a Mesureg Cynnyrch etc. (Diwygio etc.) (Ymadael â'r UE) 2019 (O.S. 2019/696) ac Atodlen 35 iddynt.

(2) O.S. 2018/390; gwnaed yr offeryn yn rhannol o dan adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 (p. 68) ac mae wedi ei arbed yn unol â hynny yn rhinwedd adran 2(2)(a) o Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 (p. 16); mae diwygiadau sy'n rhychwantu Prydain Fawr wedi eu gwneud yn rhagolygol gyda effaith o ddiwrnod cwblhau'r cyfnod gweithredu, gan O.S. 2019/696; mae diwygiadau eraill, ond nid yw'r un ohonynt yn berthnasol i'r Rheoliadau hyn.

(3) Sefydlwyd o dan adran 10 o Ddeddf Iechyd a Diogelwch yn y Gwaith etc. 1974 (p. 37).

Citation, commencement, application and interpretation

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 and come into force on implementation period completion day.

(2) These Regulations apply in relation to Wales.

(3) In these Regulations—

(a) “the PPE Regulation” (“*y Rheoliad PPE*”) means Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC(1);

(b) expressions in these Regulations which appear in the PPE Regulation have the same meaning as in the PPE Regulation;

(c) “the 2018 Regulations” (“*Rheoliadau 2018*”) means the Personal Protective Equipment (Enforcement) Regulations 2018(2).

(4) In these Regulations—

“Covid PPE” (“*PPE Covid*”) means PPE that is—

(i) necessary for protection against the coronavirus disease; and

(ii) requires conformity assessment by an approved body, in accordance with Article 19 of the PPE Regulation;

“CE marking” (“*nod CE*”) has the meaning given to it in Article 3(18) of Regulation (EU) 2016/425 (as it has effect in EU law);

“coronavirus” (“*coronafeirws*”) means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

“coronavirus disease” (“*clefyd y coronafeirws*”) means COVID-19 (the official designation of the disease which can be caused by coronavirus);

“EHSR” (“*GIDH*”) means the essential health and safety requirements applicable to the Covid PPE as set out in Annex 2 to the PPE Regulation;

(1) The PPE Regulation is incorporated into domestic law by section 3(1) of the European Union (Withdrawal) Act 2018 (c. 16) and is prospectively amended with effect from IP completion day by regulation 38 of, and Schedule 35 to, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696).

(2) S.I. 2018/390; the instrument was made in part under section 2(2) of the European Communities Act 1972 (c. 68) and is accordingly saved by virtue of section 2(2)(a) of the European Union (Withdrawal) Act 2018 (c. 16); amendments extending to Great Britain are made prospectively with effect from IP completion day, by S.I. 2019/696; there are other amendments, but none are relevant to these Regulations.

mae i “nod CE” (“*CE marking*”) yr ystyr a roddir i “CE marking” yn Erthygl 3(18) o Reoliad (EU) 2016/425 (fel y mae’n cael effaith yng nghyfraith yr UE);

ystyr “PPE Covid” (“*Covid PPE*”) yw PPE—

- (i) sy’n angenrheidiol ar gyfer diogelu rhag clefyd y coronafeirws; a
- (ii) sydd angen asesiad cydymffurfiaeth gan gorff cymeradwy, yn unol â Rheoliad 19 o’r Rheoliad PPE.

Trefniadau dros dro ar gyfer darparu bod PPE Covid ar gael

2.—(1) Nid yw’r rheoliad hwn yn gymwys ond i PPE Covid yn unig.

(2) Er gwaethaf gofynion Erthyglau 8(2), 10(2) ac 11(2) o’r Rheoliad PPE, pan fo’r amodau a nodir ym mharagraff (3) wedi eu bodloni, caniateir i weithredwr economaidd perthnasol ddarparu bod PPE Covid ar gael ar y farchnad—

- (a) cyn bod y weithdrefn asesu cydymffurfiaeth berthnasol wedi ei chyflawni; a
- (b) cyn bod nod y DU wedi ei osod arno.

(3) Yr amodau y cyfeirir atynt ym mharagraff (2), cyn bod gweithredwr economaidd yn darparu bod y PPE Covid ar gael, yw—

- (a) bod y PPE Covid wedi ei gyflwyno i gorff cymeradwy ar gyfer asesu cydymffurfiaeth; a
- (b) ar ôl i’r PPE Covid gael ei gyflwyno i gorff cymeradwy, bod yr Awdurdod Gweithredol Iechyd a Diogelwch—
 - (i) wedi asesu bod y PPE Covid yn cydymffurfio â’r GIDH sy’n berthnasol i’r broses asesu; a
 - (ii) wedi hysbysu gweithredwr economaidd ar unrhyw adeg cyn 1 Ebrill 2021 am yr asesiad bod y PPE Covid yn cydymffurfio â’r GIDH y’u haseswyd yn eu herbyn.

(4) Pan fo gweithredwr economaidd yn dibynnu ar reoliad 2A o Reoliadau 2018 ac yn cyflwyno PPE Covid i gorff a hysbyswyd, mae cyfeiriad yn y rheoliad hwn at—

- (a) nod y DU i’w ddarllen fel cyfeiriad at nod CE;
- (b) corff cymeradwy i’w ddarllen fel cyfeiriad at gorff a hysbyswyd.

“the HSE” (“*yr Awdurdod Gweithredol Iechyd a Diogelwch*”) means the Health and Safety Executive(1);

“notified body” (“*corff a hysbyswyd*”) means a conformity assessment body that is not an approved body, that has been assigned an identification number under Article 29 of Regulation (EU) 2016/425 (as it has effect in EU law).

Temporary arrangements for the making available of Covid PPE

2.—(1) This regulation applies to Covid PPE only.

(2) Notwithstanding the requirements of Articles 8(2), 10(2) and 11(2) of the PPE Regulation, where the conditions set out in paragraph (3) are met, Covid PPE may be made available on the market by a relevant economic operator before—

- (a) the applicable conformity assessment procedure has been carried out; and
- (b) the UK marking has been affixed.

(3) The conditions referred to in paragraph (2) are that before an economic operator makes the Covid PPE available—

- (a) the Covid PPE has been submitted for conformity assessment to an approved body; and
- (b) after the Covid PPE has been submitted to an approved body, the HSE—
 - (i) has assessed the Covid PPE as compliant with the EHSR relevant to the assessment process; and
 - (ii) has notified an economic operator at any time before 1st April 2021 of the assessment that the Covid PPE is compliant with the EHSR against which it has been assessed.

(4) Where an economic operator relies on regulation 2A of the 2018 Regulations and submits Covid PPE to a notified body, a reference in this regulation to—

- (a) the UK marking is to be read as a reference to the CE marking;
- (b) an approved body is to be read as a reference to a notified body.

(1) Established under section 10 of the Health and Safety at Work etc. Act 1974 (c. 37).

Trefniadau dros dro ar gyfer darparu bod PPE Covid ar gael i weithwyr gofal iechyd a gweithwyr rheng flaen eraill

3.—(1) Nid yw'r rheoliad hwn yn gymwys ond i PPE Covid yn unig.

(2) Er gwaethaf gofynion Erthyglau 8(2), 10(2) ac 11(2) o'r Rheoliad PPE, pan fo'r amodau a nodir ym mharagraff (3) wedi eu bodloni, caniateir i weithredwr economaidd perthnasol ddarparu bod PPE Covid ar gael at ddefnydd gweithwyr gofal iechyd a gweithwyr rheng flaen eraill—

- (a) heb gynnal y weithdrefn asesu cydymffurfiaeth gymwys; a
- (b) heb fod nod y DU wedi ei osod ar y PPE.

(3) Yr amodau y cyfeirir atynt ym mharagraff (2), cyn i weithredwr economaidd ddarparu bod y PPE Covid ar gael, yw—

- (a) bod y PPE Covid wedi ei brynu gan neu ar ran Gweinidogion Cymru neu un o gyrff y GIG i'w ddefnyddio yn y gwasanaeth iechyd neu mewn gwasanaethau rheng flaen eraill; a
- (b) bod yr Awdurdod Gweithredol Iechyd a Diogelwch—
 - (i) wedi asesu bod y PPE Covid yn cydymffurfio â'r GIDH sy'n berthnasol i'r broses asesu; a
 - (ii) wedi hysbysu gweithredwr economaidd ar unrhyw adeg cyn 1 Gorffennaf 2021 am yr asesiad bod y PPE Covid yn cydymffurfio â'r GIDH y'u haseswyd yn eu herbyn.

(4) Yn y rheoliad hwn—

mae i “corff y GIG” yr ystyr a roddir i “NHS body” yn adran 206 o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(1);

mae “gofal cymdeithasol” (“*social care*”) yn cynnwys pob math o ofal personol a chymorth ymarferol arall a ddarperir i unigolion y mae arnynt angen y gofal neu'r cymorth arall hwnnw oherwydd oedran, salwch, anabledd, beichiogrwydd, geni'r plentyn, dibyniaeth ar alcohol neu gyffuriau, neu unrhyw amgylchiadau tebyg eraill;

ystyr “gwasanaethau rheng flaen eraill” (“*other frontline services*”) yw darparu gofal cymdeithasol a gwasanaethau cyffuriau ac alcohol yn y gymuned ac mewn lleoliadau preswyl;

Temporary arrangements for the making available of Covid PPE for healthcare and other frontline workers

3.—(1) This regulation applies to Covid PPE only.

(2) Notwithstanding the requirements of Articles 8(2), 10(2) and 11(2) of the PPE Regulation, where the conditions set out in paragraph (3) are met, Covid PPE may be made available by a relevant economic operator for the use of healthcare and other frontline workers, without—

- (a) the applicable conformity assessment procedure having been carried out; and
- (b) the UK marking having been affixed.

(3) The conditions referred to in paragraph (2) are that before an economic operator makes the Covid PPE available—

- (a) the Covid PPE has been purchased by or on behalf of the Welsh Ministers or an NHS body for use in the health service or other frontline services; and
- (b) the HSE—
 - (i) has assessed the Covid PPE as compliant with the EHSR relevant to the assessment process; and
 - (ii) has notified an economic operator at any time before 1st July 2021 of the assessment that the Covid PPE is compliant with the EHSR against which it has been assessed.

(4) In this regulation—

“healthcare worker” (“*gweithiwr gofal iechyd*”) means an individual working as part of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006(1);

“NHS body” (“*corff y GIG*”) has the meaning given in section 206 of the National Health Service (Wales) Act 2006(2);

“other frontline services” (“*gwasanaethau rheng flaen eraill*”) means the provision of social care and community or residential drug and alcohol services;

“other frontline workers” (“*gweithwyr rheng flaen eraill*”) means any individual working in other frontline services;

(1) Mewnosodwyd adran 206 gan adran 297 o Ddeddf Iechyd a Gofal Cymdeithasol 2012 (p. 7), a pharagraffau 12 a 38(1)(b) o Atodlen 21 iddi.

(1) 2006 c. 42.

(2) Section 206 was inserted by section 297 of and paragraph 12 and 38(1)(b) of Schedule 21 to the Health and Social Care Act 2012 (c.7).

ystyr “gweithiwr gofal iechyd” (“*healthcare worker*”) yw unigolyn sy’n gweithio fel rhan o’r gwasanaeth iechyd sy’n parhau o dan adran 1(1) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(1);

ystyr “gweithwyr rheng flaen eraill” (“*other frontline workers*”) yw unrhyw unigolyn sy’n gweithio mewn gwasanaethau rheng flaen eraill.

Gorfodi

4.—(1) Pan fo gweithredwr economaidd wedi darparu bod PPE Covid ar gael gan ddibynnu ar reoliadau 2 neu 3, ni chaniateir trin y gweithredwr economaidd fel pe bai wedi mynd yn groes i’r gofynion a’r rhwymedigaethau a nodir yn Erthyglau 8(2), 10(2) neu 11(2) o’r Rheoliadau PPE at ddibenion rheoliad 7(1) o Reoliadau 2018—

- (a) os nad yw’r weithdrefn asesu cydymffurfiaeth gymwys wedi ei chwblhau mewn perthynas â’r PPE Covid; neu
- (b) os nad yw nod y DU wedi ei osod ar y PPE Covid.

(2) Mae paragraff (3) yn gymwys pan fo gweithredwr economaidd wedi darparu bod PPE Covid ar gael gan ddibynnu ar reoliad 3 a—

- (a) nad yw’r weithdrefn asesu cydymffurfiaeth gymwys wedi ei chwblhau mewn perthynas â’r PPE Covid; neu
- (b) nad yw nod y DU wedi ei osod ar y PPE Covid.

(3) Pan fo’r paragraff hwn yn gymwys, ni chaiff methiant gan weithredwr economaidd i gymryd y camau sy’n ofynnol o dan Erthygl 41(1)(b), (c) a (d) o’r Rheoliad PPE ei drin fel achos o beidio â chydymffurfio â’r Rheoliad PPE, ac ni fydd y gweithredwr yn euog o drosedd at ddibenion rheoliad 7(3) o Reoliadau 2018.

(4) Pan fo PPE wedi ei asesu gan yr Awdurdod Gweithredol Iechyd a Diogelwch cyn diwrnod cwblhau’r cyfnod gweithredu, yn unol ag Argymhelliad y Comisiwn Ewropeaidd (EU) 2020/403 dyddiedig 13 Mawrth 2020 ynghylch gweithdrefnau asesu cydymffurfiaeth a gwyliadwraeth y farchnad yng nghyd-destun bygythiad COVID-19(2), nid yw’r Rheoliadau hyn yn effeithio ar ddilysrwydd yr asesiad hwnnw gan yr Awdurdod Gweithredol Iechyd a Diogelwch.

“social care” (“*gofal cymdeithasol*”) includes all forms of personal care and other practical assistance provided for individuals who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other similar circumstances, are in need of such care or other assistance.

Enforcement

4.—(1) Where an economic operator has made Covid PPE available in reliance on regulations 2 or 3, the economic operator will not be treated as having contravened the requirements and obligations set out in Articles 8(2), 10(2) or 11(2) of the PPE Regulation for the purposes of regulation 7(1) of the 2018 Regulations if—

- (a) the applicable conformity assessment procedure has not been completed in relation to the Covid PPE; or
- (b) the UK marking has not been affixed to the Covid PPE.

(2) Paragraph (3) applies where an economic operator has made Covid PPE available in reliance on regulation 3 and—

- (a) the applicable conformity assessment procedure has not been completed in relation to the Covid PPE; or
- (b) the Covid PPE does not bear the UK marking.

(3) Where this paragraph applies, a failure by an economic operator to take the action required under Article 41(1)(b), (c) and (d) of the PPE Regulation will not be treated as non-compliance with the PPE Regulation and the economic operator will not be guilty of an offence for the purposes of regulation 7(3) of the 2018 Regulations.

(4) Where PPE has been assessed by HSE before implementation period completion day, pursuant to the European Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat(1), these Regulations do not affect the validity of that HSE assessment.

(1) 2006 p. 42.

(2) OJ L 79I, 16.3.2020, t. 1-5

(1) OJ L 79I, 16.3.2020, p. 1-5

Vaughan Gething

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol,
un o Weinidogion Cymru
9 Rhagfyr 2020

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Minister for Health and Social Services, one of the
Welsh Ministers
9 December 2020

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