

TRANSPOSITION NOTE

Directive 2014/31/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (recast)

1. This Transposition Note has been prepared by the UK's Department for Business, Energy and Industrial Strategy and is intended to explain how the 2014 Directive is implemented in the UK by the Non-automatic Weighing Instruments Regulations 2016.
2. This instrument is being made in order to implement the provisions of the recast EU Non-automatic Weighing Instruments Directive (2014/31/EU), the majority of the provisions of which came into force on 20 April 2016.
3. This instrument will replace and repeal the current Regulation (Non-automatic Weighing Instruments Regulations 2000, S.I. 2000/3236 as amended).
4. The 2016 Regulations also re-enact provisions relating to the use for trade of non-automatic weighing instruments which do not derive from obligations arising from the Directive. These are contained in Part 7 of the 2016 Regulations
5. The Secretary of State is responsible for taking measures to implement the 2014 Directive.

TRANSPOSITION TABLE FOR DIRECTIVE 2014/31

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
1(1)	Directive applies to non-automatic weighing instruments	Regulation 3(1)
1(2)	Categories of non-automatic weighing instruments to be distinguished as follows (a) determination of mass for commercial transactions; (b) determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment; (c) determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;	Regulation 3(2)

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
	<p>(d) determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment</p> <p>(e) determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;</p> <p>(f) determination of mass for the purposes of direct sales to the public and the making-up of pre-packages;</p> <p>(g) all other applications</p>	
2	Definitions	Regulation 2
3(1)	Member States shall take all steps to ensure that only instruments that meet the applicable requirements of this Directive may be made available on the market.	This obligation is implemented by implementing the substantive obligations in the Directive and ensuring that they are enforced.
3(2)	Member States shall take all steps to ensure that instruments may not be put into service for the uses referred to in points (a) to (f) of Article 1(2) unless they meet the requirements of this Directive.	Unnecessary to implement this provision explicitly. This obligation is implemented by implementing the substantive obligations in the Directive and ensuring that they are enforced.
3(3)	Member States shall take all steps to ensure that instruments put into service for the uses referred to in points (a) to (f) of Article 1(2) continue to conform to the applicable requirements of this Directive.	Unnecessary to implement this provision explicitly. This obligation is implemented by implementing the substantive obligations in the Directive and ensuring that they are enforced.
4	Non-automatic weighing instruments must meet the essential requirements set out in Annex 1 and in the relevant instrument-specific Annex	Unnecessary to implement this provision explicitly. This obligation is implemented by implementing the substantive obligations in the Directive and ensuring that they are enforced.
5(1)	Obligation not to obstruct free movement of non-automatic weighing instruments which satisfy requirements of the Directive.	Unnecessary to implement this requirement explicitly. This provision is implemented by ensuring that domestic legislation does not obstruct free movement.
5(2)	Member States shall not impede the putting into service, for the uses referred to in points (a) to (f) of Article 1(2), of instruments which meet the requirements of this Directive.	Unnecessary to implement this requirement explicitly. This provision is implemented by ensuring that domestic legislation does not obstruct free movement.

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
6(1)	When placing on the market non-automatic weighing instruments intended for the uses in Art 1(2) (a) to (f), manufacturers must ensure that they have been designed and manufactured in accordance with the essential requirements in Annex I	Regulation 6(a)
6(2)	Manufacturers must draw up technical documentation referred to in Annex II and carry out a conformity assessment procedure for instruments intended for the uses in Art 1(2) (a) to (f). Once a non-automatic weighing instrument intended for the uses in Art 1(2) (a) to (f) has, by means of a relevant conformity assessment, been demonstrated to be in conformity with the requirements of the Directive, the manufacturer must draw up an EU declaration of conformity and affix the CE marking and supplementary metrology marking.	Regulation 6
6(3)	Manufacturers must keep technical documentation and EU declaration of conformity for 10 years after the non-automatic weighing instrument has been placed on the market	Regulation 7
6(4)	Manufacturers must ensure that procedures are in place to ensure that non-automatic weighing instruments manufactured by series production remain in conformity with the requirements of the Directive.	Regulation 8
6(5)	Labelling requirements for non-automatic weighing instruments	Regulation 9 and 47(2)
6(6)	Manufacturers must indicate their name registered trade name or registered trade mark and postal address on non-automatic weighing instruments in a language easily understood by end-users and market surveillance authorities.	Regulation 10
6(7)	Manufacturers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.	Regulation 11
6(8)	Obligations imposed on manufacturers who consider or have reason to believe that they have placed on the market a non-automatic weighing instrument not in conformity with the Directive	Regulation 12
6(9)	Manufacturers must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of a non-automatic weighing instrument with the Directive in a language which can be easily understood by the market surveillance authority. Manufacturers must cooperate with the authority on action taken to eliminate risks posed by non-	Regulation 13

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
	automatic weighing instruments placed on the market.	
7(1)	A manufacturer may appoint an authorised representative who may carry out tasks on behalf of the manufacturer except the preparation of the technical documentation. Functions that must be capable of being performed by an authorised representative	Regulation 14
8(1)	Importers must place only compliant non-automatic weighing instruments on the market.	Regulation 16(1)
8(2)	Before an importer places a non-automatic weighing instrument on the market and/or puts a non-automatic weighing instrument into use, he must ensure that the manufacturer has satisfied certain obligations and that the instrument is accompanied by the required documents. Where an importer considers, or has reason to believe, that a non-automatic weighing instrument is not in conformity with the essential requirements he must not place it on the market. Where the non-automatic weighing instrument presents a risk, the importer must inform the manufacturer and the market surveillance authorities.	Regulations 16 and 17
8(3)	Importers must indicate their name, registered trade name or registered trade mark and address on the non-automatic weighing instrument.	Regulation 18
8(4)	Importers must ensure that a non-automatic weighing instrument is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned.	Regulation 19
8(5)	Importers must ensure that while a non-automatic weighing instrument is under their responsibility, storage and transport conditions do not jeopardise its compliance with the essential requirements.	Regulation 20
8(6)	When deemed appropriate with regard to the performance of a non-automatic weighing instrument, importers must, carry out certain monitoring activities and keep a register. Importers must keep distributors informed of monitoring activities.	Regulation 21
8(7)	Importers who consider or have reason to believe that they have placed on the market a non-automatic weighing instrument not in conformity with the Directive must immediately take corrective action to bring that non-automatic weighing instrument into conformity, to withdraw it or recall it. Where a non-automatic weighing instrument presents a risk, importers must immediately inform the competent national authorities of the Member States in which the article has been made available to that effect, giving details of the non-compliance and any corrective measures	Regulation 22

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
	taken.	
8(8)	Importers must keep the technical documentation and a copy of the EU declaration of conformity for 10 years after the non-automatic weighing instrument is placed on the market.	Regulation 23
8(9)	Importers must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of a non-automatic weighing instrument with the Directive in a language which can be easily understood by the market surveillance authority. Importers must cooperate with the authority on action taken to eliminate risks posed by non-automatic weighing instruments placed on the market.	Regulation 24
9(1)	When making a regulated non-automatic weighing instrument on the market available on the market and/or putting it into use, distributors must act with due care.	Regulation 26
9(2)	Distributor putting non-automatic weighing instrument must ensure that the manufacturer and importer have satisfied certain obligations and that the article is accompanied by the required documents. Where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument is not in conformity with the essential requirements he must not make it available on the market. Where the non-automatic weighing instrument presents a risk, the distributor must inform the manufacturer or the importer and the market surveillance authorities. Distributors must verify that manufacturers have complied with the requirements of Articles 6(3) and 8(3) and (5)	Regulation 27 and 28
9(3)	Distributors must ensure that while a regulated non-automatic weighing instrument is under their responsibility, they do not jeopardise its compliance with the essential requirements.	Regulation 29
9(4)	Obligations of distributors who consider, or have reason to believe, that a non-automatic weighing instrument which they have made available on the market or put into use is not in conformity.	<u>Obligation 1</u> : Regulation 30(1) and (2)
9(5)	Distributors must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of a non-automatic weighing instrument with the Directive. Distributors must cooperate with the authority on action taken to eliminate risks posed by non-automatic weighing instruments made available on the market.	Regulation 31
10	Importers and distributors to be treated as manufacturers where they place a non-automatic weighing instrument on the market under their name or modify it in a way that affects its compliance with the Directive.	Regulation 5(2)
11	Economic operators must, on request identify other economic	Regulation 32

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
	operators in the supply chain. They must be able to do this for 10 years after the supply of a non-automatic weighing instrument occurs.	
12	Non-automatic weighing instruments are presumed to be in conformity with the essential requirements to the extent that they are in conformity with a harmonised standard covering those requirements.	Regulation 35
13	Specifies the applicable conformity assessment procedures	Regulation 36
14	Requirements of the EU declaration of conformity	Regulation 40 and 41
15	Requirement to mark instrument with CE marking and supplementary metrology mark	Regulation 43
16	The CE marking is subject to the general principles in Article 30 of Regulation (EC) No 765/2008. Rules about the supplementary metrology marking to be applied to measuring instruments	Regulation 2 and 44
17	Rules relating to the application of the CE marking	Regulation 45
18	Method of affixing restrictive use symbol	Regulation 9(4)
19	Member States must notify the Commission and other Member States of bodies authorised to carry out third-party conformity assessment tasks.	Regulation 47
20	Member States must designate a notifying authority which is to be responsible for assessment and notification of conformity assessment bodies and the monitoring of notified bodies.	Regulation 48
21	Requirements to be met by a notifying authority.	It is not necessary to implement this explicitly since the relevant functions are to be performed by the Secretary of State who meets the requirements
22	Member States must inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies.	Regulations 49(7)
23	Notified body requirements	Regulation 49(4) and Schedule 3
24	Where a conformity assessment body demonstrates its conformity with the criteria laid down in relevant harmonised standards, it is to be presumed to comply with the requirements set out in Article 23 in so far as the applicable harmonised standards cover those requirements.	Regulation 50
25	Requirements where notified body subcontracts functions or these are performed by a subsidiary.	Regulation 37
26	Application procedure for notification by conformity assessment body.	Regulation 49(3)
27	Role and obligations of notifying authorities in the notification of conformity assessment bodies.	To the extent that the article imposes obligations on Member States, regulations 47(1)(b), 49(1),

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
		52, 54(5)
28	Commission obligations regarding the assignment of numbers to notified bodies	It is not necessary to implement these obligations because these are obligations on the European Commission
29	Procedure where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements relating to notified bodies	Regulation 54
30	The Commission role in relation to doubts regarding the competence of a notified body or whether the body is fulfilling its responsibilities.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
31	Notified bodies must carry out conformity assessments in accordance with the conformity assessment procedures set out in Annex II. Requirements as to how to carry out assessments	Regulation 36(4) and Schedule 2
32	Member States must ensure that an appeal procedure against decisions of the notified body is available.	Paragraph 6 of Schedule 2
33	Information required to be provided by notified bodies to notifying authorities and other notified bodies	Paragraph 7 and 8 of Schedule 2
34	The Commission must provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
35	The Commission must ensure that appropriate coordination and cooperation between notified bodies are put in place. Member States must ensure that the bodies notified by them participate in the forum.	Paragraph 9 of Schedule 2 to the extent that obligations are place on Member States
36	Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 apply to non-automatic weighing instruments.	Part 5 and Schedules 7, 8 and 9
37	Procedure where a market surveillance authority has reason to believe that a non-automatic weighing instrument presents a risk to aspects of public interest protection. Obligations of market surveillance authorities and economic operators. Role of Commission and other Member States	Regulations 2(5), 23(2), 28(2), 56(1), 57, 58(2) and 61
38	Procedure where there are objections to measures taken by a market surveillance authority in relation to non-compliant measuring instruments	Regulation 58(4),(6) and (7) to the extent that this Article requires implementation
39	Procedure where evaluation by a Member State finds that although a non-automatic weighing instrument is in compliance with the Directive, it presents a risk to aspects of public interest protection	Regulations 2(5), 59 23(2)(b) and 28(2)(b)

Article	Objective of Article	Implementation (Provision of the Non-automatic Weighing Instruments Regulations 2016)
40	Enforcement action to be taken by Member States in relation to non-compliant non-automatic weighing instruments.	Regulation 60
41	EU Committee procedure	It is not necessary to implement the obligations in this article
42	National law to have appropriate penalties for breach of the Directive's requirements	Part 9
43	Transitional provisions in relation to instruments complying with Directive 2009/23/EC	Regulation 4(4)
44	Transposition	It is not necessary to implement the obligations in this Article explicitly
45	Repeals of Directive 2009/23/EC	It is not necessary to implement this obligation explicitly.
46	Entry into force and application	Does not require transposition
47	This Directive is addressed to Member States.	It is not necessary to implement this provision.
Annex I	Essential requirements.	Definition of "essential requirements" in regulation 2
Annex II	Conformity assessment procedures.	Regulation 36 (by cross-reference to the Directive)
Annex III	Inscriptions	Schedule 1 and regulation 46
Annex IV	Model EU declaration of conformity.	Regulation 40(b) (by cross-reference to the Directive)
Annex V	Repeals and related matters	It is not necessary to implement these provisions.
Annex VI	Correlation table.	It is not necessary to implement these provisions.