
STATUTORY RULES OF NORTHERN IRELAND

1996 No. 109

HEALTH AND SAFETY

**Health and Safety (Medical Devices)
Regulations (Northern Ireland) 1996**

Made - - - - *19th March 1996*

Coming into operation *29th April 1996*

The Department of Economic Development, being the Department concerned⁽¹⁾, in exercise of the powers conferred on it by Articles 17(1), (2), (3) and (5) and 55(2) of, and paragraphs 1(1), (2) and (3), 10, 12(1) and 13 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978⁽²⁾ and of every other power enabling it in that behalf, after consultation in accordance with Article 46(1) of that Order with the Health and Safety Agency for Northern Ireland and such other bodies as appeared to the Department to be appropriate, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health and Safety (Medical Devices) Regulations (Northern Ireland) 1996 and shall come into operation on 29th April 1996.

Amendment of the Provision and Use of Work Equipment Regulations (Northern Ireland) 1993

2. In Schedule 1 to the Provision and Use of Work Equipment Regulations (Northern Ireland) 1993⁽³⁾ after paragraph 21 there shall be inserted the following paragraph—

“22. Council Directive [93/42/EEC](#) concerning medical devices (O.J. No. L169, 12.7.1993, p. 1).”

Amendment of the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993

3. In the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993⁽⁴⁾ for Schedule 1 there shall be substituted the following Schedule—

(1) See Article 2(2) of S.I.1978/1039 (N.I. 9)

(2) S.I. 1978/1039 (N.I. 9)

(3) S.R. 1993 No. 19; Schedule 1 was substituted by S.R. 1995 No. 26, regulation 2 and the Schedule

(4) S.R. 1993 No. 20 as amended by S.I. 1994/2326

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

“SCHEDULE 1

Regulation 4(3)(e)

Relevant Community Directives

1. Council Directive [89/686/EEC](#) on the approximation of the laws of the Member States relating to personal protective equipment (O.J. No. L399 30.12.89, p. 18) as amended by Council Directive [93/95/EEC](#) (O.J. No. L276, 9.11.93, p. 11) and Article 7 of Council Directive [93/68/EEC](#) (O.J. No. L220, 30.8.93, p. 1).
2. Council Directive [93/42/EEC](#) concerning medical devices (O.J. No. L169, 12.7.93, p. 1).”.

Sealed with the Official Seal of the Department of Economic Development on

L.S.

19th March 1996.

Philip B. Strong
Assistant Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations.)

1. These Regulations amend the Provision and Use of Work Equipment Regulations (Northern Ireland) 1993 by adding a new paragraph to Schedule 1 to those Regulations. Items of work equipment provided for use in the premises or undertaking of an employer must comply with any statutory provision which implements in Northern Ireland any of the relevant Community Directives listed in Schedule 1 which is applicable to such items of work equipment. The new paragraph adds to the list of relevant Community Directives contained in Schedule 1 a reference to the Medical Devices Directive, Council Directive [93/42/EEC](#) (O.J. No. L169, 12.7.93, p. 1).

2. The Regulations also amend the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993 (“the PPE Regulations”) by substituting a new Schedule for the present Schedule 1. The PPE Regulations, inter alia, specify the circumstances in which suitable personal protective equipment must be provided for use by employees and the self-employed and the minimum conditions of what is “suitable”. These conditions include that the equipment must comply with any statutory provision which implements in Northern Ireland any provision on design or manufacture with respect to health and safety in any relevant Community Directive listed in Schedule 1 to the PPE Regulations which is applicable to that item of equipment. The new Schedule 1 updates the reference to Council Directive [89/686/EEC](#) to take account of its amendment by later Directives and adds a reference to the Medical Devices Directive.