



SPETT.LE
INGEGNERIA CLINICA
O A CHI DI COMPETENZA

Termosaldatrici per chiusura buste ad uso sterilizzazione.

OGGETTO: Direttiva Europea 93/42 dispositivi medici – Recepita DI n. 46 del 24 febbraio 1997

Con la presente Vi informiamo che le termosaldatrici:


“non appartengono alla categoria Apparecchiature Elettromedicali”

Ciò è stato confermato anche dalla recente Dichiarazione Comunitaria di cui alleghiamo copia: Dichiarazione Comunitaria “European Co-ordination NB-MED” in cui al capoverso “Categoria Termosaldatrici” si dichiara quanto segue: NB-MED (Coordinamento Europeo Enti Notificatori Apparecchiature Medicali) ha deciso che le termosaldatrici sono solo apparecchiature di processo (vedere anche NBM/105/97). **Un accessorio ad un accessorio di un’apparecchiatura medicale non è un dispositivo medicale.**

Per quanto sopra le termosaldatrici non fanno riferimento alla **norma 62-5 ed alle relative classificazioni (classe-tipo).**

GANDUS SALDATRICI SRL

Cornaredo, Settembre 2000

	<p>Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC and 93/42/EEC</p>	<p>Consensus statements</p>
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distribution chain)?" N. A. explained that the council in the context of IVDD set a "cut off date". Those products which have been placed on the market by June 15, 1998 can still reach the final user until June 30, 2001. There will be a re-definition of the concept of "putting into service", in fact it will mean these products can be transferred to the final user until June 30, 2001. Products which e.g. left by manufacturer into an hospital but are not used by the hospital are placed on the market; they have even been put into service and can be used. The payment and the ownership are not conditions for placing a product on the market or for putting into service. The question is: "Is the product available e.g. for the physician?" In this case the product has been put into service.

14. Meeting NB-MED on 24./25.06.97, Item 6.6

(NBRG-Meeting on 11./12.06.98: see also „communication document“ made by the Commission, distributed on the NB-MED meeting on 09./10.06.98 as document NBM/102/98.)

(Remark of the Technical Secretariat: see also „communication document“ NBM/150/98.)

S/27/97 Categorisation of devices for preparation of solution bags

NB-MED decided that this presented device for preparation of solution bags has not to be considered as a medical device or as an accessory to a medical device.

15. Meeting NB-MED on 18./19.11.97, Item 3.4 (1)

(NBRG-Meeting on 11./12.06.98: No further action required.)

S/28/97 Declaration specifying that no application has been lodged with any other Notified Body for the same product/product related quality system

The Notified Bodies made practicable proposals for a solution. E.g. in the application form between Notified Body and the manufacturer, the manufacturer should declare „No other application has not been made to an other Notified Body“. Normally the manufacturer declares that he has not been involved with an other Notified Body. In the case that such an declaration is not given the „new“ Notified Body requests from the manufacturer to release his former Notified Body from the obligation of confidentiality versus the „new“ Notified Body; than the „new“ Notified Body could make contact with the former Notified Body.

15. Meeting NB-MED on 18./19.11.97, Item 3.4 (2)

(NBRG-Meeting on 11./12.06.98: No further action required.)

S/29/97 Categorisation of thermosealing machine

NB-MED decided that a thermosealing machine is only a processing equipment (see also NBM/105/97). An accessory to an accessory of a medical device is not a medical device.

15. Meeting NB-MED on 18./19.11.97, Item 3.4 (3)



“Consensus statements“

of Notified Bodies Medical Devices

(NB-MED)

on Council Directives 90/385/EEC and 93/42/EEC

(completed by comments of the Notified Body Recommendations Group - NBRG)

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