

According to: *Annex I- Essential requirements - of the Medical Device Directive 93/42/EEC*
Annex VII - EC declaration of conformity - of the Medical Device Directive 93/42/EEC
Annex IX – Criteria for classification - of the Medical Device Directive 93/42/EEC

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Versionsnummer av dokument/Version of document:	03
Tillverkare/Manufacturer:	Sonesta Medical AB
Affärsområde/Division:	Sonesta
Adress/Address:	Grev Turegatan 3 114 46 Stockholm Sweden
Medicinteknisk produkt/Medical Device:	
Klassificering enligt Annex IX (93/42/EEC)/ Classification according to Annex IX (93/42/EEC)	

Produktidentifikation (Artikelnr) / Device identification (Part No.):			
<i>Produkt namn/ Product Name</i>	<i>Artikelnr/ Part No.</i>	<i>Beskrivning, Version, etc. / Description, Version, etc.</i>	<i>Tillverkare/ Manufacturer</i>
	525-S3		Sonesta Medical AB



EG-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE EC DECLARATION OF CONFORMITY

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Vi intygar härmed att ovanstående medicintekniska produkt uppfyller tillämpliga krav i lag (1993:584) om medicintekniska produkter samt i Läkemedelsverkets föreskrifter LVFS 2003:11 om medicintekniska produkter. Produkten uppfyller härigenom även kraven i direktiv 93/42/EEG och RoHS direktivet.

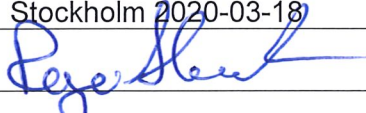
Ändringar av produkten, som ej godkänts av Sonesta Medical AB gör denna deklaration ogiltig.

Koncernen är certifierad enligt ISO 9001:2015 och 14001:2015

We declare the compliance of the medical device concerned with the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2003:11 of the Medical Products Agency. Hereby, the medical device complies with the requirements of the Medical Device Directive 93/42/EEC and RoHS directive.

Any modification to the device, not authorised by us, will invalidate this declaration.

The group is certified according to ISO 9001:2015 and 14001:2015

Ort och datum/Place and date:	Stockholm 2020-03-18
Namnteckning/Signature:	
Namnförtydligande/Printed name:	Roger Henriksson CEO