

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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|---|---|
| Dokumentnummer/Document No:   | S2-16CE001  |
| Versionsnummer av dokument/Version of document:   | 02  |
| Tillverkare/Manufacturer:   | Sonesta Medical AB  |
| Affärsområde/Division:  | Sonesta   |
| Adress/Address:   | Grev Turegatan 3<br>114 46 Stockholm<br>Sweden  |
| Medicinteknisk produkt/Medical Device:  | Bord för undersökning/behandling inom gynekologi/examination.<br>Treatment table for gynaecological examination and procedures. |
| Klassificering enligt Annex IX (93/42/EEC)/<br>Classification according to Annex IX (93/42/EEC) |   |

| Produktidentifikation (Artikelnr) / Device identification (Part No.): |                                |  |                                      |
|---|--------------------------------|--|--------------------------------------|
| <i>Produkt namn/<br/>Product Name</i>                                 | <i>Artikelnr/<br/>Part No.</i> | <i>Beskrivning, Version, etc. /<br/>Description, Version, etc.</i>   | <i>Tillverkare/<br/>Manufacturer</i> |
| S2  | 525-S2                         | Gynekologibord och urologibord, med två elektriska motorer för höjd och sätesreglering, manuell styrd ryggdel.<br>Gynaecology and urology table, with two electric motors for height and seat adjustments, manually controlled back section. | 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.

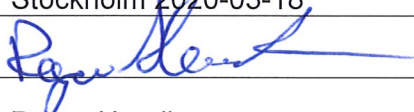
Ändringar av produkten, som ej godkänts av Sonesta Medical AB gör denna deklaration ogiltig.

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   |
| Befattning/Position:            | CEO  |