




EC DECLARATION OF CONFORMITY

Date Prepared:	7 Oct, 2019		
Place Prepared:	Lyra Medical Ltd. office		
EC Declaration of Conformity reference	Design Dossier SRS rev. B		
Manufacturer:	Lyra Medical Ltd.		
Lyra Medical Ltd. office address:	3 Hamelacha Binyamina, Israel 3057324 Tel.: +972-4-99221100 Fax: +972-73-2714042		
Postal Address:	P.O 273 Kerem Maharal Israel 3084000		
Authorized Representative:	MedNet GmbH		
Address:	Borkstraße 10, 48163 Münster, Germany Tel: +49 (0) 251 322 66-61 Fax: +49 (0) 251 322 66-22 ear@mednet-europe.com www.mednet-eurep.com		
Product:	Lyra Self-Retaining Support (SRS)		
Product Numbers:	SRS70-00 or 6001399		
Product lot/batch numbers	170724, 170725-1, 170725-2, 190114, 190224, 190225, 190623, 190729, 190915-1, 190915-2, 191222, +191224		
Classification:	Class IIb Rule 8 of Annex IX of MDD 93/42/EEC: +191224		
Conformity Assessment Route:	93/42/EEC Annex II (Excluding Section 4)		
GMDN Code	60842: Pelvic organ prolapse surgical mesh, synthetic polymer		
<p>We ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, Rule 8 of Annex IX of MDD 93/42/EEC meet the provisions of the EC-Directive, which apply to them. This declaration is supported by the Quality System Certificate according to the harmonized standard EN ISO 13485:2016 with reference number 31824601, initially issued on 3.9.2018 and delivered by SZUTEST.</p> <p>This Declaration of Conformity covers the product/s specified below and is valid for all products concerned bearing the CE marking</p> <p>All supporting documentation including declaration of conformity are under the responsibility of Lyra Medical Ltd. and retained under the premises of the manufacturer.</p>			
Notified Body:	SZUTEST Uygunluk Değerlendirme A.Ş		
Address:	Local Office Yukarı Dudullu Mh. Nato Yolu Cd. Çam Sk. No:7 Ümraniye - İstanbul / TÜRKİYE		
Identification Number:	2195		
EC Certificate:	2195-med-1824601		
Date CE Mark was First Affixed:	3.9.2018		
Place of Declaration Issue:	3 Hamelacha Binyamina, Israel		
Signature:		Date:	Oct 7, 2019
Name and Title:	Iram Levit CEO		