

EC DECLARATION of CONFORMITY

We, as **Ligamed Tıbbi Malzemeler Sanayi ve Ticaret Ltd. Şti.** (Address: Site Mah. Baha Sok. Koza Palace No: 2/3 Ümraniye İSTANBUL), hereby declare that; our product models that are manufactured at **Metrosan Endüstriyel ve Elektromekanik Cihazlar ve Tıbbi Malzemeler Sanayi ve Ticaret Ltd. Şti.** (Address: İsmail Kahraman Caddesi No:1 M.O.S.B. 4. Kısım Manisa / TÜRKİYE), with the given classes and GMDN codes according to the 93/42/AT Medical Device Directive ANNEX IX are produced in compliance with the following standards and guides, all supporting documentation is retained under the premises of our company,

All standards and provisions of 93/42/EEC Medical Device Directive,

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2021, EN ISO 10993-11:2018, EN ISO 14602:2011, EN ISO 16061:2021, EN ISO 14630:2012, EN ISO 11737-2:2020; EN ISO 21534:2009; ISO 5832-3:2016; ISO 12189:2008; ISO 13782:2019; ASTM F543:2016; ASTM F1717:2015; ASTM F136:2013; ASTM F2026:2016; ASTM F2193:2014; ASTM F1789:2013; ASTM F2077:2018; ASTM F2346:2018.

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4) is selected as Conformity Assessment Route.

Product Name	Model Name	Basic UDI-DI	Class	Rule	GMDN Code
BIOMECH Cervical System Products	The model list of non-sterile product is located in CE.LS.01.01.Product List.	The basic UDI-DI codes of non-sterile products are located in CE.LS.01.01.Product List.	IIb	8	38161 48164 61865 37272 61325

The compliance of our products to the above-mentioned directives and documents is confirmed by the notified body, **UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti.** (ID number: 2292, Address; **Mutlukent Mahallesi 2073. Sokak No:10 Ümitköy-Çankaya-Ankara / Türkiye**), with the European Commition Product Conformity Certificate that is given below:

Previous Certificate No	: MDD-O-C-043/16
Previous Certificate Issue Date	: 20.06.2016
Previous Certificate Valid Date	: 05.05.2021

Certificate No	: M.2016.106.7277
Certificate Issue Date	: 05.12.2016
Certificate Valid Date	: 27.05.2024
Certificate Revision No / Date	: 1 / 14.04.2021
Start of CE Marking of Lot Number	: -

By Approved	: İbrahim Ayberk SELÇUK	Signature
Title	: General Manager	
Issue Date	: 09.07.2014	
Issue Place	: İstanbul, TÜRKİYE	
Declaration Revision No	: 10	
Declaration Revision Date	: 18.04.2022	

Declaration of Company Quality System and Continuity

We, as **Ligamed Tıbbi Malzemeler Sanayi ve Ticaret Ltd. Şti.** (Address: Site Mah. Baha Sok. Koza Palace No: 2/3 Ümraniye İSTANBUL), declare that our products that are manufactured in **METROSAN Endüstriyel ve Elektromekanik Cihazlar ve Tıbbi Malzemeler Sanayi ve Ticaret Ltd. Şti.**, facilities located in **İsmail Kahraman Caddesi No:1 M.O.S.B. 4. Kısım Manisa / TÜRKİYE** and whose model, classification according to 93/42/EEC Medical Devices Directive Annex II (Excluding Section 4), and GMDN codes are provided below, are manufactured in compliance with the standards and guidelines.

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4) is selected as Conformity Assessment Route.
EN ISO 13485:2016 Quality Management System,

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2021, EN ISO 10993-11:2018, EN ISO 14602:2011, EN ISO 16061:2021, EN ISO 14630:2012, EN ISO 11737-2:2020; EN ISO 21534:2009; ISO 5832-3:2016; ISO 12189:2008; ISO 13782:2019; ASTM F543-2016; ASTM F1717:2015; ASTM F136:2013; ASTM F2026:2016; ASTM F2193:2014; ASTM F1789:2013; ASTM F2077:2018; ASTM F2346:2018.

We declare that all requirements of the quality system of the product which is produced in accordance with above mentioned standards and guidelines will be fulfilled, quality system will be continued completely and effectively, a system was established for the purpose of reviewing the data which is obtained from production and this system will be updated, the required corrective actions are performed like which is indicated in 93/42/EEC Medical Devices Directive- Annex II (Excluding Section 4).

Product Name	Model Name	Basic UDI-DI	Class	Rule	GMDN Code
BIOMECH Cervical System Products	The model list of non-sterile product is located in CE.LS.01.01.Product List.	The basic UDI-DI codes of non-sterile products are located in CE.LS.01.01.Product List.	IIb	8	38161 48164 61865 37272 61325

The conformity of our products with the directives and documents above are approved with the certificate whose information provided below, by the notified body **ROYALCERT Belgelendirme ve Gözetim Hizmetleri A.Ş.**, located in **Kar Plaza, E Blok, Kat:13, 34752, Ataşehir-İstanbul / Türkiye.**

Certificate No : 5085/LİG13A

Certificate Issue Date : 23.12.2020

Certificate Valid Date : 08.01.2023

Certificate Revision No : 01

Certificated Revision Date : 04.01.2019

By Approved : İbrahim Ayberk SELÇUK

Title : General Manager

Issue Date : 09.07.2014

Issue Place : İstanbul, TÜRKİYE

Declaration Revision No : 10

Declaration Revision Date : 18.04.2022

Signature