

# E.A.R CERTIFICATE

Article 11 of Regulation (EU) 2017/745 on Medical Device

<b>Reference</b>	IN01524	<b>SRN NO</b>	IN-MF-000036712	<b>Issue Date</b>	26 Jul 2024
<b>Manufacture</b>	NEOTECH MEDICAL PVT. LTD		<b>Facilities</b>	41, Iupati Industrial Estate, Near Amber Cinema, Saraspur, Ahmedabad, Gujarat 380024 (INDIA)	
<b>Product Categories</b>	Please See Annexure-A List of Devices ( 12 Devices & 02 pages)				
<b>Models</b>	Please See Annexure-A List of Devices ( 12 Devices & 02 pages)				

The European Authorized Representative Center, AF Pharma Service Europe SL declares it will assume the role of European authorized representative of the aforementioned manufacturer, provided that the manufacturer complied with terms and conditions set out in EAR Service Agreement which entered into force on 14-July-2023 and the mandate is signed by both parties in accordance with article 11.2 of MDR (EU) 2017/745. This certificate has no legal value. Compliance with standards, directive and regulations is the sole responsibility of the manufacturer of the devices.



**Maria Agustina Duguine**  
AF Pharma Service SL owner

**AF PHARMA SERVICE EUROPE S.L.**  
CIF: B67780684  
European Union

**AF Pharma Service**  
**is playing role of**  
**Authorized**  
**Represented under**  
**Actor ID/SRN - ES-**  
**AR-000018076**

This certificate is neither a certificate of product notification nor an approval to place product on the market. The certificate will become void automatically upon termination EAR Agreement or rejection of products from PRRC of AF Pharma Service.

**Valid up to 14 July 2025.**

**Registered Address:** AF Pharma Service Europe SL, Muntaner – 281, City: Barcelona España Postal Code: 08021, Country: Spain - **Contact information:** [info@afpharmaservice.com](mailto:info@afpharmaservice.com), [www.afpharmaservice.com](http://www.afpharmaservice.com).

**Urgency phone:** +34 648988915

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## Annexure- A List of Device

**Issue Date** 26 July 2024

EMDN Name	EMDN Code	Basic UDI-DI
GENERAL MEDICINE INSTRUMENTS – OTHER	Z120499	8908021134GENERALMED5H
VARIOUS OPHTHALMOLOGY INSTRUMENTS	Z121290	8908021134OPHTHALMOLOGYRD
VARIOUS ENT INSTRUMENTS	Z121490	8908021134ENTINSTRUMENTB6

EMDN Name	Product Name	Product Code/ MODEL NO
GENERAL MEDICINE INSTRUMENTS -OTHER	1. Surgeons Chair	SC-2000
	2. General Examination Chair	GE-2000
	3. Doctors Seating Chair	DS-2000, DS-2000 Plus
	4. Instrument Trolley	PH-2000
	5. Power Instrument Table	IT-2000,IT-2001, IT-2002,IT-2003, IT-2003/S,
VARIOUS OPHTHALMOLOGY INSTRUMENTS	6. Ophthalmic Refraction Unit	NEO-2021, OU-2000, OU-2001, OU-2003, OU-2010, OU-2017, NEO Smart, NEO Advance, NEO-RF-16, NEO-9009
	7. Arm For Phoropter	PA-2000
	8. Ophthalmic Examination Chair	GE-2000

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<b>EMDN Name</b>	<b>Product Name</b>	<b>Product Code/ MODEL NO</b>
	9. Ophthalmic Operation Table	OT-2000, OT-2001
	10. Vision Testing Drum	VD-2000
	11. Digital Distance Vision LED Chart	NEO-LED
VARIOUS ENT INSTRUMENTS	12. ENT Specialist Chair	EC-2000



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