Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, MDSS GmbH agrees to perform all duties and responsibilities as the Authorized Representative for:

Aditya Dispomed Products Pvt. Ltd.
Plot No. 19, Sector 6, I.M.T. Manesar
122050 Gurgaon, Haryana
INDIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated May 07, 2025

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC.

The devices are covered by this Certificate as long as MDR 2017/745 Article 120 (3) applies to them. The applicability is evaluated by and under responsibility of the Manufacturer. MDSS has to be informed once that Article is no longer applicable.

In addition, the applicability may be supported by evidence documents in accordance with the "Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607". Devices for which the Notified Body (NB) Certificate(s) show(s) an end of period in the past are only covered by this Certificate if they are covered also by evidence documents referenced in attached Annex A.

This Certificate is valid without signature and can be traced within MDSS' electronic system.

Certificate No.: 876192

Annex A dated May 07, 2025
Manufacturer: Aditya Dispomed Products Pvt. Ltd.

Evidence documents regarding applicability of MDR Art. 120 (3): Manufacturer declaration (signature date): *Revised_Final_MDR_Manufacturer_Declaration 26-04-2025 (26-04-2025)* NB's confirmation letter (signature date): *C670077 (07.02.2024)*						
UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	**UMDNS Code**	**Risk Class**	**Cat. Code**	**Registration Number**	**NB No. / NB Certificate No.**	**End date of period indicated on the NB Certificate YYYY-MM-DD**
Blades	15-558	IIa	10	DE/CA09/00059535	2460/11174-2017-CE-IND-NA-PS	2024-05-27
Gouge Blades in Carbon Steel & Stainless Steel						
Gouge Blades (Sterile) in Carbon Steel & Stainless Steel: 1, 1V, 2, 2V, 2M, 3, 3V, 4, 5, 6, 8, 10, 12, 15						
Knives, Scalpel	12-252	IIa	10	DE/CA09/00059536	2460/11174-2017-CE-IND-NA-PS	2024-05-27
Disposable Scalpels in Carbon Steel & Stainless Steel with or without Twin Rib						
Disposable Scalpels (Sterile) in Carbon Steel & Stainless Steel with or without Twin Rib blade and with and without Safety features: 9, 10, 10A, 11, 11P, 12, 12D, 13, 14, 15, 15A, 15C, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 24D, 25, 25A, 26, 27, 34, 36, 36D, 60, PM40, PM40B, PM60, PM60B, Mini Stitch Cutter						
Knives, Blades	12-234	IIa	10	DE/CA09/00059537	2460/11174-2017-CE-IND-NA-PS	2024-05-27
Surgical Blades (Sterile) in Carbon Steel & Stainless Steel with or without Twin Rib						
devices as listed on "Doc No. F 7.2-25 Rev.04" (signed 03-10-2024)						
Cutter, Suture	16-224	IIa	10	DE/CA09/00071431	2460/11174-2017-CE-IND-NA-PS	2024-05-27
Stitch Cutter Blades in Carbon Steel & Stainless Steel with or without Twin Rib						
Stitch Cutter Blades (Sterile) in Carbon Steel & Stainless Steel with or without Twin Rib: Long, Standard and Mini						