

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
287125-2019-AQ-IND-NA-PS

Initial certification date:
29 May 2019

Valid:
16 January 2022 – 15 January 2025

This is to certify that the management system of

Premier Enterprises

S.F 39/2, DOOR NO.136/9 SOUTH STREET, SANKARAPANDIAPURAM, CHATRAPATTI,
RAJAPALAYAM TALUK, VIRUDHUNAGAR DISTRICT - 626102, Tamil Nadu, India

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Manufacture and Supply of Sterile and Non-Sterile Medical disposables such as Gauze Swabs (Plain & X-Ray), Lap Sponges (Plain & X-Ray), Nasal Pack (Plain & X-Ray), Cut Gauze, Gauze Ball, Absorbent Cotton Gauze, Neuro Gauze, Gamjee Pad & Roll, Post Surgery Dressing Pad, Roller Bandage, Dressing Kit and Dialysis Kit.

Manufacture and Supply of Non-sterile Bleached Cotton Fabrics for Medical Disposables.

Place and date:
Høvik, 19 January 2022



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Appendix to Certificate

Premier Enterprises

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Premier Enterprises	S.F 39/2, DOOR NO.136/9 SOUTH STREET, SANKARAPANDIAPURAM, CHATRAPATTI, RAJAPALAYAM TALUK, VIRUDHUNAGAR DISTRICT - 626102, Tamil Nadu, India	<p>Manufacture and Supply of Sterile and Non-Sterile Medical disposables such as Gauze Swabs (Plain & X-Ray), Lap Sponges (Plain & X-Ray), Nasal Pack (Plain & X-Ray), Cut Gauze, Gauze Ball, Absorbent Cotton Gauze, Neuro Gauze, Gamjee Pad & Roll, Post Surgery Dressing Pad, Roller Bandage, Dressing Kit and Dialysis Kit</p> <p>Manufacture and Supply of Non-sterile Bleached Cotton Fabrics for Medical Disposables</p>
Premier Enterprises	S.F 30, DOOR NO.532B,532C,532D NORTH STREET, SANKARAPANDIAPURAM, CHATRAPATTI, RAJAPALAYAM TALUK, VIRUDHUNAGAR DISTRICT - 626102, Tamil Nadu, India	<p>Manufacture and Supply of Sterile and Non-Sterile Medical disposables such as Gauze Swabs (Plain & X-Ray), Lap Sponges (Plain & X-Ray), Nasal Pack (Plain & X-Ray), Cut Gauze, Gauze Ball, Absorbent Cotton Gauze, Neuro Gauze, Gamjee Pad & Roll, Post Surgery Dressing Pad, Roller Bandage, Dressing Kit and Dialysis Kit</p>
Premier Enterprises	NO.770 & 773, KEELAVALLANADU, VALLANADU, SRI VAIKUNDAM TALUK, Thoothukudi District - 628252, Tamilnadu, India	<p>Manufacture and Supply of Non-sterile Bleached Cotton Fabrics for Medical Disposables</p>