

RAYS SPA

Registered and Operative Site: Via Francesco Crispi, 26 - 60027 OSIMO (AN) - ITALY

Bureau Veritas Italia S.p.A. certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

Standard

EN ISO 13485:2012

Scope of certification

Production management of the and marketing of sterile surgical gloves, sterile single use plasters, sterile and non-sterile medical devices in hydrophilic cotton and nonwoven gauze, sterile single use needles and syringes, sterile surgical coats, infusion/transfusion sets and related single use sterile disposable accessories, active medical devices for the monitoring of vital physiological parameters. Design management, production and marketing of non-sterile single use gloves, urine collection bags, non-sterile single use medical devices in non-woven gauze, hydrophilic cotton gauzes and non-sterile gauze swabs, non-sterile hydrophilic cotton wool, sterile plasters and dressing with hydrogel. Marketing of non-active and nonimplantable medical devices for wounds care and measurement system devices.

Certification awarded in conformity with the requirements of ACCREDIA DT 02-DC REV.00

Certification cycle start date: 29 April 2017

Subject to the continued satisfactory operation of the organisation's Management

System, this certificate expires on: 28 February 2019

Original certification date: 14 September 2005

Certificate No. IT266120

Version N.2 Revision date: 05 May 2017

ANDREA FILIPPI Local Technical Manager

Certification body address:

Bureau Veritas Italia spa, Via Miramare, 15, 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management

system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website http://www.bureauveritas.it/certificate

