



OM Institutional Ethics Committee

IEC Registration#: ECR/1168/Inst/GJ/2018/RR-22

August 27, 2022

To.

Mr. Vikas Salgotra

Study Coordinator

Sahajanand Laser Technology Ltd.

A-8, G.I.D.C, Electronic Estate,

Sec-25, Gandhinagar-382016,

Gujarat, India. Telephone No: +917923287461

Dear Mr. Vikas Salgotra,

The OM Institutional Ethics Committee reviewed your additional application to conduct the clinical trial entitled “**A retrospective, single-arm, multi-center, observational, post-market clinical follow-up study to evaluate the safety and performance of FlexyRap Cobalt Chromium Rapamycin Eluting Coronary Stent System in patients with *de novo* coronary artery disease under real-world settings.**” On August 27, 2022.

Study Code: SLTL/ FlexyRap DES-1

The following documents were reviewed:

1. List of Study Investigators
2. CV and MRC of Investigators
3. PSP of Investigators

Site details and Investigators list:

Sr. No	Site Name	PI Name
01	Cardinova Hospital, 292, Near Guru Nanak Mission Chowk, Lajpat Nagar, Jalandhar, Punjab 144001	Dr. Nitish Garg
02	Caremax Hospital, 333, Near Guru Nanak Mission Chowk, Shastri Nagar, Lajpat Nagar, Jalandhar, Punjab 144001	Dr. Raman Chawla

Address: OM CHILDREN HOSPITAL, 304-305, Silver Star Commercial Complex, Silver Star Cross Road, New Chandlodia, Ahmedabad – 382 481; **Tel#:** 9712018187; **Email:** omch.iec@gmail.com



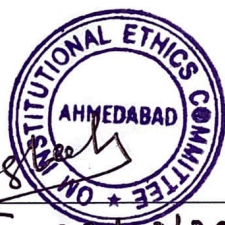
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03	EMC Super Speciality Hospital, Backside Income Tax office, Green Avenue, Amritsar, Punjab 143001	Dr. Vivek Tandon
04	Moga Medicity Multispecialty Hospital, Near Radha Vallabh Mandir Wali Gali, Dutt Rd, Civil Lines, Shanti Nagar, Moga, Punjab 142001	Dr. Deepak Garg
05	Sunshine Global hospital, Dumas Rd, beside Big Bazar, Piplod, Surat, Gujarat 395007	Dr. Nilesh Parshottam

The Ethics Committee approves this additional application based on expedited review; however other conditions as defined in the initial approval letter dated March 19, 2022, will be remained the same.

Yours sincerely,



Signature & Date

Dr. Vipul Shah

Member Secretary, OM IEC

24/08/2022