



Episurf Medical reaches important regulatory milestone in India

Episurf Medical (Nasdaq: EPIS B) today announces that the Indian authorities have, through their Directorate General of Health Services, Central Drugs Standard Control Organisation (CDSCO), Medical Devices Division, confirmed that the Episealer® Knee implant portfolio represents a Custom Made device that can be imported to India in accordance with the rules for Custom Made devices. This classification follows a review process, and represents an important regulatory milestone for Episurf Medical, as it enables a market expansion in the Indian market. Episurf Medical has been targeting the Indian market for several years, but a final decision on the regulatory classification was needed before commercial activities via its subsidiary Episurf India Ltd could be initiated at a larger scale.

"All the work performed by us in India, while waiting for this regulatory decision, has confirmed that there is a large clinical need for patients who are between biological procedures and knee replacement prostheses. Surgeons are clearly struggling with this patient group, and we will now go ahead with our plans to introduce the Episealer® Knee implant portfolio in India. The fast growing Indian healthcare market represents a significant commercial opportunity for us, and we can finally take the next steps," says Pål Ryfors, CEO, Episurf Medical.

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About Episurf Medical

Episurf Medical is endeavoring to bring people with painful joint injuries a more active, healthier life through the availability of minimally invasive and individualised treatment alternatives. Episurf Medical's Episealer® individualised implants and Epiguide® surgical drill guides are developed for treating localised cartilage injury in joints. Episurf Medical's µFidelity® system enables implants to be cost-efficiently tailored to each individual's unique injury for the optimal fit and minimal intervention. Episurf Medical's head office is in Stockholm, Sweden. Its share (EPIS B) is listed on Nasdaq Stockholm. For more information, go to the company's website: www.episurf.com.