Amendment No. 14

Date- 19-12-2023

Sub: Amendment No.14 to the Tender Enquiry Document

Ref: (i) Tender No: HITES/PCD/RML/02/MIX/23-24 dated 28-07-2023

For Tender ID- 2023_HITE_ 162696_4 – Nerve Integrity Monitor

Section VII
Technical Specifications

Item No 4: Nerve Integrity Monitor		
Tender spec Para	**TENDER SPECIFICATION**	**READ AS**
1	Surgeon Directed/Controlled (SD) and Neurophysiologist Supported (NS) capabilities in one system.	Hand held probe and Neurophysiologist Supported (NS) capabilities in one system.
10	Should include two operational modes i.e., Surgeon Directed (SD) and Neurophysiologist Supported (NS). Surgeon Directed (SD) mode should also incorporate feature of SD advanced option which shall allow few advanced parameters of NS module to be used in SD mode for higher end applications.	Should include two operational modes i.e., Hand held probe and Neurophysiologist Supported (NS) capabilities
	SD Features	Deleted
1	System should be operable by the operating surgeon from the sterile field via a sterile probe which allow surgeon to increase or decrease current, change the monitoring test mode and print reports.	Deleted
2	An exclusively dedicated 8-Channel module (preamplification and stimulation in a single box) capable of recording EMG. Trig EMG, Screw testing, Nerve Proximity, MEP and train of four modalities.	Deleted
3	2-channel pulse Ox recording.	Deleted
4	Automated report generation for pedicle screw stimulation.	Deleted
5	Fully surgeon controllable from the sterile field with the help of surgeon-controlled probe having buttons to give access to system parameters and test modalities	Deleted
6	Probe should allow the surgeon to select the modality, adjust the current and deliver the stimulus directly from the sterile field.	Deleted
7	Probe's multicolor LED indicates test results.	Deleted
8	Multiple manual and triggered EMG modes of operation	Deleted
9	Audible and visual surgeon feedback.	Deleted
	Nerve Proximity Features	
3	Should provide all neural monitoring instruments for XLIF procedure along with audio tone feedback.	Deleted
	US FDA Approved	
1	The system should be USFDA approved for use	The system should be USFDA/European CE/BIS approved for use

Note: If EMD is submitted in the form of BG, then the validity of the BG should be at least 775 days from the date of tender opening.

All other terms and conditions of the tender enquiry remain unaltered