ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI – 110029 (Burns & Plastic Surgery Block)

Ref. No. B&PS/66/Non-Invasive Monitor/PAC/2024-25

Dated: 03.05.2025

Sub:- Purchase of "Non Invasive Real Time Patient Monitoring System- 25 nos." from M/s Turtle Shell Technologies Pvt. Ltd., Bengaluru on Proprietary basis (PAC)- reg.

Store Section has initiated a proposal for purchase of "Non Invasive Real Time Patient Monitoring System- 25 nos." from M/s Turtle Shell Technologies Pvt. Ltd., Bengaluru, on Proprietary basis (PAC). User department has submitted PAC certificate duly signed by departmental TSEC. M/s Turtle Shell Technologies Pvt. Ltd., Bengaluru has also submitted proprietary certificate and Authorization letter.

As per prevailing guidelines issued from the office of CPO vide No. Policy/CPO (AIIMS)/2012 dated 01.11.2012 wherein there is a provision to upload the details of the item on the website for the open information for a period of 15 days to submit objections, if any by any manufacture regarding proprietary nature of the equipment/item and thereafter, the proposal shall be submitted to TSEC, Store Purchase Committee and Competent Authority for approval. With regard to above said guidelines, the soft copy of details PAC of OEM had been obtained and prepared with covering letter for uploading in the Institute website i.e. www.aiims.edu for open information from any bidder/firm.

The comments should be received by office of Stores Officer (BPS), AIIMS on or **before** 19.05.2025 upto 12.30 p.m., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Stores Officer (BPS)

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, ANSARI NAGAR, NEW DELHI

Department of Plastic, Reconstructive & Burns Surgery

PROPRIETARY/ SPECIFIC BRAND GOODS CERTIFICATE

| 1 | Item/ Type/ Model No. required along with Specifications | Non-invasive Patient Monitoring System, Name, Type etc enclosed | | | |
|---|---|--|--|--|--|
| 2 | Is the item a spare part attachment or accessory for existing equipment | No | | | |
| 3 | Name of the Manufacturer/ Supplier of the item proposed by the indenter | Turtle Shell Technologies Pvt. Ltd. (TST) | | | |
| 4 | Are the Sole Manufacturer/ Sole Distributor of the item | Yes | | | |
| 5 | Is there any other item with similar/ equipment specifications available in the market to meet the job requirement envisaged? If the answer is yes, why the same can't be procured? | No | | | |
| 6 | What were the efforts made to locate alternative source of supply or use other substitutes? | Checked online/ offline and not available on GeM Portal | | | |
| 7 | Why Open/ limited tender can't be resorted to, for locating alternative source? | As per online and offline available information, the above- mentioned item uses patented technology for monitoring of patient parameters which is not available with any other vendor. | | | |
| 8 | Are the Proprietary items certifying that the rates are reasonable or not | Yes | | | |
| 9 | Any other justification for procuring item for single source | The item is best used for burns patients where due to non-availability of healthy skin for invasive monitoring. Thus, with the help of fully Make In India patented non-invasive technology, basic patient parameters can be monitored without causing much discomfort to the patients where advanced parameters are not needed. | | | |

Signature of Indentor (Demanding Officer)

Marred Spi (Counter Signed)

(Head of the first ment) aneesh Singhal आचार्य एवं अध्यक्ष/Professor & Head

It is certified that above-mentioned item is required to be procured on single a sist का the source विभाग of the supply is definitely known and limited tender system could be dispensed with supply is definitely known and limited tender system could be dispensed with supply the supply is defined by the no useful purpose in this particular case. Also, market survey has been done and found that no other manufacturer is manufacturing similar equipment which can fulfil vital requirements of the department.

शरांक चौहान/Dr. Shashank Chauhan अपर आचार्य/Additional Professor प्लास्टिक पुनसंरचना और सन्ध शल्य चिकित्सा विभाग Department of Plastic , Reconstructive & Burns Surgery अ.भाजा.स.,अंसारी नगर, नई दिल्ली-110029

का कुमार मानस/Dr. Raj Kumar Manas अपर आचार्य/Additional Professor प्लास्टिक पुनसंरवना और दन्ध रूल्य विकित्सा विभाग Department of Plastic , Reconstructive & Burns Surgery अ.भा.अ.स. ,असरी नगर, नई दिल्ली-110029 A.H.M.S., Ansai Nogar, New Dalbi-110020

डो. जियांगी साहा/Dr. Shivangi Saha सहायक आचारां/Assistant Professor जलन एवं दशस्टिक चिकित्सा विभाग -Burns & Plastic Surgery Block अस्रेवल शास्त्रीय आयुर्विज्ञान संस्थान/A. I.M.S नई दिल्ली/New Delhi-1*0050

File No. B&PS/66/NonInvasiveMonitor/PAC/2024-25 (Computer No. 3291534)

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Drug Lig. No. 10 (1330) GSTIN: 07ARLPS5238E1ZJ

NEHRA BROTHERS

Distributors for :

LIFE SAVING MEDICINES & MEDICAL EQUIPMENTS

21, NEW MARKET, RAMESH NAGAR, NEW DELHI- 110 015

Ref No. NB/AIIMS/2024-2025/003

To The Head of Department All India Institute of Medical Sciences Ansari Nagar , New Delhi - 110029

Subject: Quotation for Drozee Pro NX

Ref : Department of Plastic, Reconstructive and Burns Surgery

Dear Sir.

Please find mentioned below our rate quotation of the following item for your institute

| S.No. | Description of Goods | A/U | Rate in INR | Qty | Amount (Incl. GST) |
|-------|---|-----|-------------|-----|--------------------|
| 1 | Dorzee Pro NX Make : Turtle Sheel Technologies Pvt.Ltd. | Pcs | 2,65,000 | 1 | 265000.00 |

Terms & conditions

- 1. Dilivery : within 30-40 days of the confirmed supply order
- 2. Payment : As per Hospital Terms
- 3. FOR Hospital Stores
- 4. Warranty: 2 years, CMC: 8 Years

Looking forward for your valuable Orders

For Nehra Brothers

FOR NEHRA BROTHERS

Authoriesped Buth Signetory



Turtle Shell Technologies Private Limited

No. 40, City Centre, Chinmaya Mission Hospital Road, Bengaluru (Bangalore) Urban, Karnataka 560038

Date: 08/05/2024

PROPRIETARY ARTICLE CERTIFICATE

This is to certify that Turtle Shell Technologies Pvt. Ltd. (TST) at No. 40, City Centre, Chinmaya Mission Hospital Road, Bengaluru, Karnataka - 560038 is the sole manufacturer (CDSCO License No: MFG/MD/2024/000207) and marketer of indigenously developed, proprietary Dozee Pro NX device and the accompanying Secure RPM software.

Further, Dozee Pro NX is protected by 14 patents (pending approval), filed in India as well as internationally and 2 US Patents (numbered US 11,751,772 and US 11,793,426) have already been granted which shall be valid for 3.5 years from the year of grant i.e 2023 which can be further extended upto 20 years. Hence, the said product and software are proprietary in nature.

Sincerely

Gaurav Parchani

CTO & Director

Turtle Shell Technologies Pvt. Lident

डा. राजा तिवारी/Dr. Raja Tiwari सह आधार्य/Associate Professor जलन एवं प्लास्टिक चिकित्सा विभाग Burns & Plastic Surgery Block अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S. नई दिल्ली/New Delhi-110029

संघल/Dr. Maneesh Singhal

w/w.dctee.health

AILMS A

contact@dozee.ia

बोहान्/Dr. Shashank Chauhan

and Additional Professor

Burns & Plastic Surgery JA 1 1 K

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+918884436933



CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/165-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER:

WELLYSIS Corp.

1111ho, 311, Gangnam-daero, Seocho-gu, Seoul 06628, KOREA

DEVICE/S:

Wearable health monitoring system

MODEL/S:

S-Patch Cardio

✓ S-Patch Ex

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डो. प्रशाक चौहान/Dr. Shashank Chauhan
अपर आचार्य/Additional Professor
अपर आचार्य/Additional Professor
अपर आचार्य/Additional Professor
अस्त प्रसार/Additional Professor
अस्ति श्री स्वारित के सिकित्सा विभाग
अस्ति श्री श्री स्वारी/ALLIM S.
अस्तिन भारतीय आयुर्विज्ञान संस्थान/ALLIM S.

FIRST ISSUE: 22

22/04/2020

CURRENT ISSUE: 07/0

07/05/2021

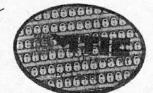
REVISION Nr.: 01

डॉ, मनीप सिंघल/Dr. Maneesh Singhal आधार्य एवं राज्यहा/Professor & Head प्लास्टिक पुनरारकार के किला विभाग

Department of Plasti , Burns Surgery st 41.51.

हां राजा तिवारी/Dr. Raja Tiwari प्राचन प्रे प्लारिटक विकरता विभाग Burns & Plastic Surgery Block अधिव भारतीय आयुर्विज्ञान संस्थान/ALLMS. नई दिल्ली/New Delhi

EXPIRING DATE: 27/05/2024



Dipl.- Ing. Feridoon Sergizzarea

KAT * SERTIFIKA * CERTIFICADO * a a LA A C * DIA PORTORIA

MTIC INTERCERT S.r.l. - Via Moscova, II - 20017 RHO (MI) - ITALY www.mtic-group.org 12 info@mtic-group.org

CERTIFICATE CERTIFICA

No. B&PS/66/NonlinvasiveMonitor/PAC/2024-25 (Computer No. 3291534)



FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2024/000207

- 1. M/s Turtle Shell Technologies Private Limited, 40. City Centre, Ground And Mezzanine Floor CMH Road, Indiranagar Bengaluru Bangalore KA 560038 INBengaluru, Bengaluru (Bangalore) Urban, Karnataka (India) - 560038 Telephone No.: 9738044710 FAX: 9738044710 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s TURTLE SHELL TECHNOLOGIES PRIVATE LIMITED. First Floor, No 7 & 8, 12th Cross, Kodichikkanahalli Main Road, Bommanahalli, Kaveri Nagar, Bengaluru (Bangalore) Urban, Karnataka (India) - 560076 Telephone No.: 9738044710 FAX: 9738044710
- 2. Details of medical device(s) [Annexed]
- 3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
- 4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

| S.No. | Details Of Device(s) |
|-------|---|
| | Generic Name:Vital Signs Monitor and Early Warning System |
| 1 | Model No.:Dozee Pro NX-S - 1 x Dozee Pro pod 2 x Sensor Sheet 1 x Adapter |
| | Secure RPM software 1 x Wired SpO2 Sensor 1 x Wired Temperature Sensor ,Dozee |
| | Pro NX-A - 1 x Dozee Pro pod 2 x Sensor Sheet 1 x Adapter Secure RPM software1 x |
| | Wireless SpO2 Sensor 1 x Wireless Temperature Sensor |
| | Intended Use: The Dozee Pro NX is a patient monitoring device intended for use by |
| | healthcare professionals for the measurement of multiple physiological parameters. |
| | The physiological parameters include the Heart Rate, Respiration Rate, Non-invasive |
| | Blood Pressure, Skin Temperature, Oxygen Saturation, and Movement of the patient. |
| | These are measured using a combination of contactless sensors as well as wired and |
| | wireless accessories. These parameters are stored, displayed and reported - |
| | centrally and remotely. The device includes the ability to notify healthcare |
| | professionals when a physiological parameter falls outside selected thresholds. This |
| | device is intended for patients who are 18 years of age or older weighing above 40 |
| | kgs and below 120 kgs. The device is intended for patients in non-critical healthcare |
| | settings. |
| | Class of medical device:Class C |
| 1 | Material of construction:ABS Plastic, Circuit Board, Piezoelectric Sensor Sheet |
| 1// | Dimension(if any):Different components have different dimensions |
| JV | Shelllife:16 Months Charles as Non-sterilis Non-Sterilised |
| | Sterile or Non sterile:Non-Sterilized |
| | Brand Name(if, registered under the Trade Marks Act, 1999):Dozee Pro NX |

Place

Date 28-Mar-24

RAJEEV SINGH RAGHUVANSHI

Central Licensing Authority

File No. B&PS/66/NonInvasiveMonitor/PAC/2024-25 (Computer No. 32915, 14 Conf. Now Delhi-110029

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Certificate of Registration

INFORMATION SECURITY MANAGEMENT SYSTEM - ISO/IEC 27001:2013

This is to certify that:

TURTLE SHELL TECHNOLOGIES

PRIVATE LIMITED

City Centre, #40 Ground & Mezzanine flr, Nomads Daily Huddle

Chinmaya Mission Hospital Rd, Indiranagar

Bengaluru 560 038

Karnataka India

Holds Certificate No:

IS 748635

and operates an Information Security Management System which complies with the requirements of ISO/IEC 27001:2013 for the following scope:

> The Information Security Management System applies to the company's Product and Services in the Healthcare sector, supported by Product & Technology and enabling support functions. This is in accordance with the Statement of Applicability ver 1.1 dated 3rd Nov 2021.

For and on behalf of BSI:

डॉ. मनीप लिंचले Dr. Maneesh Singhal ापवार्य वर्ग अध्यक्ष/Professor & Head प्लास्टि

Michael Lam - Managing Director Assurance, APAC

Department Surgery

Original Registration Date: 2021-12-09 Latest Revision Date: 2021-12-09

Effective Date: 2021-12-09

Expiry Date: 2024 में2-08ा तिवारी/DA Raja Tiwari

सह आवार्य/Associated Professor जुलन एवं ज्यारिक प्रमाशन विभाग विधान से Plastic Surgery Block अखिल मारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.

making excellence a habit

be authenticated online.



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Turtle Shell Technologies Private Limited

Main Site: City Centre # 40, Ground & Mezzanine Floor Nomads Daily Huddle, Chinmaya Mission Hospital Road Indiranagar, Bengaluru - 560038, Karnataka, India

Additional Site: Turtle Shell Technologies Private Limited # 32, Fourth Floor, CMH Road, Bangalore - 560038, Karnataka, India

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Design and Development, Manufacturing, Distribution, Installation and Service of Monitoring Devices of Physiological Parameters (Vitals) such as Heart Rate, Respiratory Rate, SpO2, Temperature, Blood Pressure, and Sleep parameters.

Dr. Maneesh Singhal ा जायम/Professor & Head

ोर दग्ध शत्य िकित्सा विभाग acconstructive & Burns Surgery नगर, नई दिल्ली-110023

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BUTHS & Plastic Surgery ALLANS.

THE TREATMENT AND ALLANS. Rem Delhi-110029

डॉ. राजा तिवारी/Dr. Raja Tiwari

Certificate Number:

0124226

Initial Certification Date:

12 May 2022

Date of Certification Decision:

12 May 2022

Issuing Date:

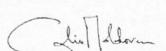
20 May 2022

Valid Until:

11 May 2025







Calin Moldovean

President, Business Assurance

Intertek India Private Limited, F-Wing, 2nd Floor, Tex Centre, Chandivali Farm Road, Andheri (East), Mumbai - 400072, India

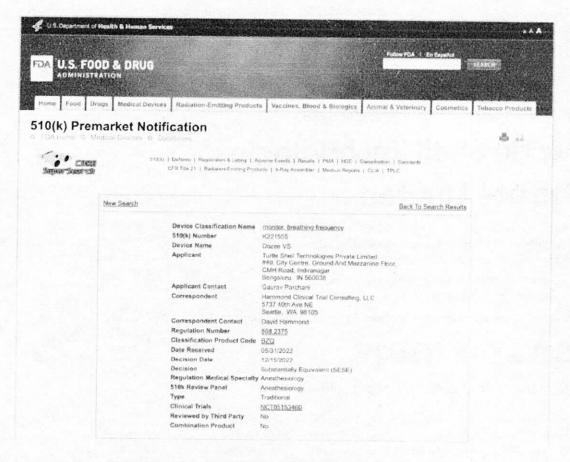
Intertek India Private Limited is a NABCB accredited body under schedule of accreditation no. QM033.



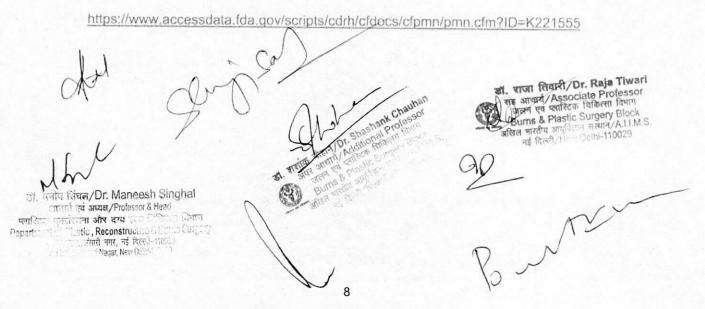
सर्व आरार्य Associate Professor अस्त्रिक चारिक चिकित्सा विभाग Burns & Plastic Surgery Block अखिल भारतीय आयोजना संस्थान/A.I.I.M.S. in the issuance of this certificate, intertek assumes no hability to any party other than to the Clie Agreement. This certificate's validity is subject to the organization maintaining their system in accordance may be confirmed via email at certificate validation@intertek.com or by scanning the code to the right with a smartpho to whom it must be returned upon request.

File No. B&PS/66/NonInvasiveMonitor/PAC/2024-25 (Computer No. 3291534)

Dozee FDA 510 (k) Number: K221555



Please find the 510(k) Premarket Notification database link for Dozee VS.



Item name: Non invasive real time Patient monitoring system

PRODUCT SPECIFICATIONS

Electrical Specifications

- Adapter Input Voltage: 100~240VAC, 50/60Hz, 1A
- Adapter Output: 5V, 4A
- Device Power Consumption: 4W (+/- 10%)

Communication Specifications

- WiFi (802.11b/g/n) (2.412 GHz~2.462 GHz); EIRP: 15dBm (+/-2dBm)
- BLE 4.2 (2.402 GHz~2.480 GHz); Channel BW: 1MHz; EIRP: 6dBm (+/-2dBm)
- Antenna Gain & Type: 2dBi & PCB Antenna Sensor Technology
- The device uses piezoelectric sensors to capture vibration data
- The device uses force sensing resistors to capture user movement Vital Parameter Specifications
 - Heart Rate Measurement Range: 30 170 bpm (MAE ± 3 bpm)
 - Respiration Rate Measurement Range: 6 45 rpm (MAE ± 2 rpm)
 - Oxygen Saturation Range: 70 100 % (Accuracy: ±2%(80%~100%); ±3%(70%~79%))
 - NcBP (Non Contact Blood Pressure) Range
 - Systolic Range: 90 170 mmHg
 - Diastolic Range: 50 110 mmHg
 - NiBP (Non-Invasive Blood Pressure) Range
 - Systolic Range: 80 200 mmHg (±10 mmHg)
 - Diastolic Range: 40 120 mmHg (±10 mmHg)
 - Temperature Range: 91.4 104.0 °F (MAE ±1.8 °F)

User Conditions

- User Weight: 40~120 Kgs
- BMI: 33.77 kg/m2 73.86 kg/m2
- Supported Mattress: Foam, Memory Foam, Spring, Coir
- Mattress Thickness: 2~16inches Operating Conditions
- IP Rating: IP22

Physical Characteristics (+/- 5%)

- Pod Dimensions: 130mm x 80mm x 60mm
- Sensor Sheet 1 Dimensions: 750mm x 250mm x 9.5mm
- Sensor Sheet 2 Dimensions: 750mm x 125mm x 9.5mm
- NiBP Module Dimensions: 162mm x 100mm x 50mm
- Bed Sleeve Dimensions: 1540mm x 760mm
- Device Mounting Stand Dimensions: Height: 1320mm, Base: 360mm x 360mm

Package content

- Pod x 1
- Sensor Sheet x 2 with connector cable
- SpO2 Probe (Silicone, Adult Clip) x 1
- NiBP Module with Connector, Cuff, Type C Cable x 1
- Temperature Sensor Probe x 1
- Power Adapter x 1
- Bed Sleeve x 1
- Mounting Stand x 1
- Instructions for Use x 1

प्लास्टिक Department of Plan ALLMS

Singhal Head ेल्सा विभाग ourns Surgery

A THINK FOR





Turtle Shell Technologies Private Limited

No. 40, City Centre, Chinmaya Mission Hospital Road, Bengaluru (Bangalore) Urban, Karnataka - 560038

Date: 08/05/2024

PROPRIETARY ARTICLE CERTIFICATE

This is to certify that Turtle Shell Technologies Pvt. Ltd. (TST) at No. 40, City Centre, Chinmaya Mission Hospital Road, Bengaluru, Karnataka - 560038 is the sole manufacturer (CDSCO License No: MFG/MD/2024/000207) and marketer of indigenously developed, proprietary Dozee Pro NX device and the accompanying Secure RPM software.

Further, Dozee Pro NX is protected by 14 patents (pending approval), filed in India as well as internationally and 2 US Patents (numbered US 11,751,772 and US 11,793,426) have already been granted which shall be valid for 3.5 years from the year of grant i.e 2023 which can be further extended upto 20 years. Hence, the said product and software are proprietary in nature.

Sincerely

Gaurav Parchani

CTO & Director

Turtle Shell Technologies Pvt. Ltd.

www.dozee.health

Shashank Chauhan illional Professor

+918884436933

डॉ. मनीप सिंघल/Dr. Maneesh Singhal

आधार्य एवं अध्यक्ष/Frolessor & Head प्लास्टिक युनसंस्कान और कृत कर विकित्सा विभाग