

IN THE HIGH COURT OF JUDICATURE AT PATNA
Civil Writ Jurisdiction Case No.8935 of 2022

1. Wring Nano Systems Pvt. Ltd. through Abhishek Anand Male, aged about 42 years, Son of Anand Mohan Prasad, the Regional Sales Manager, ground floor, khesra no. 329 and 335, Village- Naryal, Parwanoo Tehsil Kasauli, Selan, Himachal Pradesh- 173220.
2. M/s SRL Trading Company through Ritesh Kumar, aged about 42 years, S/o Late Shivbrat Prasad, the Manager, SRL Trading Company, Opposite Arya Samaj Mandir, 2nd Floor, Keshri Complex, S.N. Road, Upper Bazar, Ranchi- 834001.

... .. Petitioner/s

Versus

1. The Bihar Medical Services and Infrastructure Corporation Limited in short BMSICL, through its Managing Director, 4th Floor, Bihar State Building Construction Corporation Ltd. Hospital Road Shastri Nagar, Patna.
2. The Managing Director, Bihar Medical Services and Infrastructure Corporation Limited (BMSICL).
3. The General Manager (Procurement) BMSICL, Patna.
4. The Union of India through Ministry of Commerce and Industry, Department of Commerce, Government of India, New Delhi.
5. The Secretary Ministry of Commerce and Industry, Department of Commerce, Govt. of India, New Delhi.
6. The National Accreditation Board for Certification Bodies (NABCB) through its Chairman, Institute of Engineers Building, New Delhi- 110002.
7. The Chairman the National Accreditation Board for Certification Bodies (NABCB) the Institute of Engineers Building, New Delhi- 110002.
8. The C.E.O., NABCB the Institute of Engineers Building, New Delhi- 110002.
9. The M/s Sensa Core Medical Instrumentation Pvt. Ltd., Plot No. 3, export import promotion Industrial Park, Pashamylaram, Sangareddy District- Hyderabad, Telangana- 502307
10. The M/s Sysmed Exim Pvt. Ltd., SCO 1-2-3, 2nd Floor, Sector 17B, Chandigarh- 160017

... .. Respondent/s

Appearance :

For the Petitioner/s	:	Mr.Prabhu Narayan Singh, Sr. Advocate
For the State	:	Mr. Birju Prasad, GP-13
		Mr. Ravi Kumar, AC to GP-13
		Ms. Shweta Anand, AC to GP-13
For Respondent Nos. 1 to 3:		Mr. Lalit Kishore, Sr. Advocate
		Mr. Vikash Kumar, Advocate
		Mr. Sriram Krishna, Advocate
For Respondent No. 9	:	Mr. Umesh Prasad Singh, Sr. Advocate



Mr. Vaibhava Veer Shankar, Advocate

CORAM: HONOURABLE MR. JUSTICE P. B. BAJANTHRI
and
HONOURABLE MR. JUSTICE A. ABHISHEK REDDY
ORAL JUDGMENT
(Per: HONOURABLE MR. JUSTICE P. B. BAJANTHRI)

Date : 17-05-2023

Heard learned counsels for respective parties.

2. In the instant writ petition, petitioners have prayed
for the following reliefs:-

"(i) For quashing of the order of the Technical Committee, which has been taken in its meeting held on 29th April 2022 for evaluation of Technical bids, with reference to Tender no. BMSICL/2020-21/ME-253, under the Chairmanship of Director in Chief, Department of Health, Govt of Bihar only to the extent of the petitioner's company firm by which, the petitioner's firm was illegally on none-est ground declare technically disqualified.

(ii) Also for commanding the Respondents to declare Petitioner's firm/ Company Technically qualified as the petitioner's firm/ Company having all quality and qualify each and every conditions under the tender document for supply of Digital Haemoglobinometer (Hb Meter).

(iii) Also for commanding the respondents to allow the petitioner's firm/ Company to participate in the Technical demonstration of requisite Tender Procurement article i.e Digital Haemoglobinometer (Hb Meter) etc.

(iv) Also for commanding the respondent to make proper enquiry as to the certification of the petitioner's company i.e Wring Nanosystem Pvt. Ltd. and during the period of enquiry get the Tender proceeding stay.

(v) Also for commanding the



respondents to supply the email communication of NABCB dated 11.04.2022 by which it has been said to communicate that the certificate no. Q-9101021991 is suspended dated 01.02.2020 to the petitioner's company/ firm.

(vi) Also for commanding the respondents National Accreditation Board for Certification Bodies, hereinafter referred as NABCB, to review the opinion in priority in context with the tender requisites and not otherwise.

(vii) And also for any other relief/ reliefs for which the petitioner's company/ firm found entitled on the facts and in the circumstances of the present case."

3. Pursuant to N.I.T. dated 14.01.2022 tender was issued for procurement, rate contract and supply of the Digital Haemoglobinometer (Hb Meter), Test Strips/ Cuvettes and Auto Disable Lancets for different Government Health Institutions of Bihar. Petitioners and five others participated in the bid process. Petitioners' bid was rejected in the Technical Evaluation on the score that the petitioners' certificate relating to ISO 9001:2015 to the extent that it is not an authenticated document. The petitioner feeling aggrieved by the rejection of his bid in the Technical Evaluation, presented this petition.

4. Learned counsel for the petitioner submitted that the decision of the authority to reject the petitioners' bid on the score that his certificate no. Q-9101021991 is stated to have been suspended on 01.02.2020 as well as the Certification Body being accredited by UAF, USA which itself is not IAF MLA



signatory accreditation body and such certificate cannot be considered authentic under international accreditation system. Thereafter, pursuant to the opinion expressed by the NABCB, the certificate is not under accreditation. In support of genuineness of the certificate, the learned counsel for the petitioners submitted that his certificate was in order and not suspended and it was in vogue during the intervening period from 01.02.2020 to 31.03.2023. During the intervening period there were two surveillance on 31.01.2021 and 31.01.2022. The certificate issued by TCCPL itself reveals that it is a member of IAF MLA. Therefore, the respondent authority's decision to reject the petitioner's Technical Evaluation is not in order and it is arbitrary. Further, learned counsel for the petitioner relied on Form MD-5, suffice to contend that the certificate is in order. It is also submitted that NABCB recorded its remarks against 9th Respondent. The certificate produced by the 9th Respondent is also defective.

5. *Per contra*, learned counsel for the respondents-authority submitted that the certificates produced by the bidders were forwarded for verification to NABCB and obtained opinion relating to certificates produced by each of the six bidders. Petitioners' bid was examined by the NABCB and found that certificate was suspended. Thereafter, once again it was sent for



verification, it has expressed that TCCPL, author of the certificate is not a member of IAF/ MLA. Taking note of the opinion expressed by NABCB, petitioners have not made out a case. It is also submitted that such procedure has been considered under the Medical Device Rules 2017. In this regard, learned counsel for the respondent- authority pointed out Rule 11(1), Rule 12 and Rule 13 in support of material information provided by NABCB and rejection of the petitioner's Technical Evaluation Bid.

6. Learned counsel for the 9th respondent resisted the petitioners' contentions and submitted that there is no infirmity of the rejection of petitioners' Technical Evaluation Bid in the light of the opinion expressed by NABCB.

7. Heard learned counsels for the respective parties.

8. Core issue involved in the present *lis* is whether petitioner is eligible to participate in the bid with reference to N.I.T. dated 14.01.2022 and his Technical Bid is in order or not? One of the condition stipulated in N.I.T. is production of certificate of ISO 9001:2015 and other equivalent certificates. The petitioner had produced certificate of ISO which reads as under:-

"TCCPL
Certificate of Registration
This is to certify that

Wrig Nanosystems Private Limited
170. IInd Floor, Patparganj Industrial Area, New
Delhi-110 092 (New Delhi) INDIA



has been assessed and registered by TCCPL as conforming to the requirements of

ISO 9001:2015

[Quality Management System]

The Quality Management System is applicable to:

**Design, Development, Manufacture and Sale of
In Vitro Diagnostic Devices for Haematology,
Immunology & Biochemistry**

Certificate No: Q-9101021991 Certificate issue
date: 01-02-2020 Certificate valid till 31-01-2023
1st Surveillance due before: 31-01-2021 | 2nd
Surveillance due before 31-01-2022

Managing Director"

9. In order to ascertain genuineness of the
aforementioned certificate of the petitioners and others,
respondent -authority forwarded the papers including certificate
of five others to NABCB for its opinion. NABCB provided its
opinion, which reads as under:-

"Member IAF & ILAC
IAF MLA for QMS, EMS, Product
FSMS, ISMS, Global G.A.P., EnMS
OHSMS, MDQMS & Personnel Certification
ILAC MRA for Inspection
APAC MRA for GHG, ICAO CORSIA & FSSC 22000

*National Accreditation Board
for Certification Bodies*

Shri Sudhir Kumar, B.A.S
GM (Procurement)
Bihar Medical Services and Infrastructure
Corporation Limited (BMSICL)
4th Floor,
Hospital Road, Shastri Nagar,
Patna-800023, Bihar

Subject: Regarding verification of Quality Standards Certificate for Digital
Haemoglobinometer – Reply

Reference: (i) Your Letter No. BMSIC/45025/430-2021/10181 dated
29.03.2022 received vide email dated 01 April 2022

(ii) NABCB Letter dated 11 April 2022

(iii) Representation of M/s Wrig Nanosystems Pvt. Ltd. dated



6 May 2022 received from BMSICL vide mail dated 11 May 2022
Sir,

With reference to the email representation of M/s Wrig Nanosystems Pvt. Ltd. alongwith the documents forwarded to NABCB by BMSICL, the point-wise response is attached at Annex-1.

Further, NABCB has done due diligence of the documents/ certificates received from BMSICL vide Initial mail dated 01 April 2022 based on the information available in public domain and has provided its inputs/comments.

We would further like to inform you that the representing / bidding company M/s Wrig Nanosystems pvt. Ltd. has been approaching NABCB directly to pursue its representation, and BMSICL/ Bihar Govt may like to take necessary action, if any, against the company as per the procedures.

With my best regards,

Sincerely yours,

(Rajesh Maheshwari)
CEO (NABCB)

As per the tender criteria, the following clauses were mentioned for certification:

- i. Quality Standard certification (FDA/CE/BIS/ISO etc as required in the technical specification) for specification on for each schedule of requirement if any.
- ii USA FDA/ European CE/Any other equivalent certification
Preferable: ISO 9001:2008 certification

As per the released notification following grounds have been used for the disqualification of our bid, below mentioned are the points and their respective clarification:

1. Bidder has submitted ISO Certificate ISO 9001:2015, ISO 13485:2016

(a) But as per NABCB email dated: 11.04.2022 the ISO 9001:2015 Certificate no. Q-9101021991 is suspended dt. 01.02.2020 as well as the Certification Body (CB) being accredited by UAF, USA which itself is not IAF MLA Signatory accreditation body and thus this certificate cannot be considered authentic under international accreditation system.

Clarification:

- i. The ISO 9001:2015 certificate no: **Q-9101021991** submitted has been issued on 1.02.2020 by the certification body and is valid II 31.01.2023. It's clear from the documentation that 1st February is the issuing date.

Also, **the certificate is valid and active as per the status of the certification body**, the link is mentioned below:



<https://uafaccreditaon.org/Home/Certificate:OrganisationName=WRIG:SchemeNo=9;RegistrarNo=6>

NABCB Response: The above-mentioned certificate issued by TCCPL (Certificate Number: Q- 9101021991) was verified as suspended (Dated: 5 April 2022), when checked by NABCB prior to the submission of response to BMSICL. However, to support the authenticity of the NABCB remarks, please refer to the following screenshot.

However, we have again verified the same certificate on the TCCPL website (Dated: 12-05-2022) for which the status is reflected as active. BMSICL may seek confirmation from Wrig Nanosystems Private Limited if its ISO 9001 certificate was suspended on the date of submission of tender bid and ask for the details, if any.

ii. The tender criteria had no clear guidelines about the type of certification on or the Signatory accreditation body i.e. **there was nowhere mentioned in the tender or in the corrigendum that the accreditation body needs to be a part of IAF MLA.** While as per prevailing standards and the articles by NABCB ex-CEO, *the Accreditation body needs to be a member of IAF which our Accreditation body (AB) duly complies with.* Also, note that use of IAF Mark is optional and its absence does not necessarily mean the certificate is not intentionally equivalent.

NABCB Response: As per IAF website, UAF is still not IAF MLA signatory and only act as a member.

Further, please refer serial number 4 of the article provided by Wrig Nanosystems which itself clearly states that "*If the certificate carries logo of AB also, check if the AB is part of the IAF (international Accreditation Forum) system-its name can be checked from IAF website www.iaf.nu for each country. **If the AB is listed there, the certificate is likely to be genuine. If not, the certificate is not the authentic** and seek an authentic certificate under IAF system."*

Nevertheless, there are number of articles published worldwide on authentication of certificates and NABCB does not endorse such articles,

Kindly note that ISO 9001 2015 certificate issued for TCCPL under UAF accreditation does not have IAF MLA Mark, which itself signifies that it is not an authentic certificate under International system of accreditation.

As per the current scenario it seems NABCB hasn't investigate the genuineness/validation of the certificate properly neither a communication was sent to UAF requesting credibility of the certification nor have given any opportunity to TCCPL/Wrig



Nano systems to clarify on the matter, which is against the nature of justice, if so, there must be evidence of the arbitrary disqualification.

NABCB Response: The above statement that NABCB has not investigated, is not warranted and hence invalid. NABCB has done due diligence of the documents provided. It is not obligatory on part of NABCB to communicate with external bodies as long as the information is available in public domain.

The tender requirements for certification in the technical criteria were: **"USA FDA/European CE/Any other equivalent certification Preferable: ISO 9001:2008 Certification"**. We, Wrig Nanosystems have proactively submitted all our documents including ISO and CE (Declaration of Conformity).

BMSICL has accepted the same CE document from other bidders (Biosense-Sysmed) and has kept silent about our certification. Also, there's no mentioned the ISO of other co-bidders being from non- accredited bodies, **there is no mention of our CE certificate and we have been disqualified based on ISO, which stands valid and authenticated by the Accreditation Body, full Member of IAF.**

NABCB Response:

NABCB had received the certificate as in Picture 1 from BMSICL vide mail dated 01 April 2022 whereas one of the certificate (EC Declaration of Conformity) is different as received from BMSICL vide mail dated 11 May 2022.

10. In the light of opinion expressed by NABCB, it is evident that petitioners' certificate cited (supra) is not genuine for the reasons that TCCPL is not a member of IAF and MLA as indicated in the certificate. Such opinion has been expressed by NABCB with reference to Website of the IAF M.L.A to the extent that whether TCCPL is member IAF and M.L.A. or not? In this backdrop, the petitioner has not apprised this court to contend that TCCPL is member of IAF and MLA. In the absence of material information that TCCPL is a member of IAF and MLA, there is no infirmity in rejection of the petitioners' Technical Evaluation with reference to opinion expressed by the NABCB. It is necessary to take note of



Rule 11(i), Rule 12 and Rule 13 of the Medical Device Rules, 2017. Reading of these Rules, it is evident that National Accreditation Body and its functioning including notified body. Therefore, NABCB is competent authority to determine the validity of certificate of ISO cited (Supra) of the petitioners among others.

11. The petitioners have not assailed the validity of 9th Respondent's certificate is genuine or not? In the absence of questioning the certificate of the 9th Respondent in the present petition, the contention of the petitioner that 9th Respondent's certificate is not in order, cannot be examined.

12. In view of the these facts and circumstances, petitioners have not made out a case. Accordingly, the present writ petition stands dismissed.

13. The interim order granted by this Court ceases since the main matter is disposed of in the light of Apex Court decision rendered in the case of *Kalabharti Advertising Vs. Hemanth Vimal Nath Narichania* reported in *(2010) 9 SCC437*.

(P. B. Bajanthri, J)

(A. Abhishek Reddy , J)

Rakhi/ Namita

AFR/NAFR	NAFR
CAV DATE	N.A.
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