



MEDEXCOM-TEH SRL  
IDNO 1019600008809  
Str. Cuza Vodă 44, of. 111, mun. Chisinau,  
Republica Moldova

**To: PI “CIMU HSP”**  
**RFB No.: MDA/T/GD/NCB-4**  
**LP ocds-b3wdp1-MD-1776946754822**

**Certified copy / documents confirming possibility of placing the medical device on the market**

We, Medexcom-Teh SRL, confirm that the proposed Digital X-Ray unit and related accessories can be placed into circulation and/or use in accordance with the applicable technical regulation requirements.

We also submitted the quality certificates for the offered equipment:

- **CE Certificate of Conformity** issued by a Notified Body (NANDO-listed)
- **EC Declaration of Conformity**
- **Quality system certificate – ISO 13485**
- **MDR Notified body confirmation letter**

We confirm that the offered medical electrical equipment complies with the applicable safety and essential performance standards, in particular **EN 60601-1** (General requirements for basic safety and essential performance) and, where applicable to the offered configuration, the relevant particular standard **EN 60601-2-44**.

Compliance with the above standards has been used as part of the **conformity assessment** supporting the issuance of the **CE marking documentation**

**At the same time, we confirm that the offered equipment will be placed into circulation in accordance with the legislation in the field of technical regulation and conformity assessment, as provided by law.**

Name of the Bidder - MEDEXCOM-TEH SRL

Name of the person duly authorized to sign the Bid on behalf of the Bidder - ANDREI MATEI

Title of the person signing the Bid - Managing director(Administrator)

Signature of the person named above -