

Directorate of Health Safety & Regulation
Red Cross Building Near Raj Bhawan
Himachal Pradesh, Shimla-02

F.No.HSR-H(PNDT)(USG Reg.)1145/2021

Dated:

Preamble:

The PC & PNDT Act enacted by the Parliament of India to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.

As per the provision of Act under Section 16A & 17 the State Supervisory Board, State Appropriate Authority, State Advisory Committee, District Appropriate Authority, District Advisory Committee has been notified by Government of Himachal Pradesh.

In order to curb the unauthorized sale / circulation of USG/ imaging machines and as per Notification dated. 24.2.2014 from Ministry of Health & Family Welfare, wherein Rule 18(A)7) shall observe the guideline for manufacture, retailer, distributor.

All Appropriate Authorities including the State, District notified under the Act, inter-alia, shall observe the following regulation of ultrasound equipments namely:

- (i) Monitor the sales and import of ultrasound machines including portable or buy back, assembled, gift, scrap or demo;
- (ii) Ensure regular quarterly reports from ultrasound manufacturers, dealers, wholesalers and retailers and any person dealing with the sales of ultrasound machine at the State level
- (iii) Conduct periodical survey and audit of all the ultrasound machines sold and operating in the State or District to identify the unregistered machines,
- (iv) File complaint against any Owner of the unregistered ultrasound machine and against the seller of the unregistered ultrasound machine

Guidelines for Sale, Distribution of Ultrasound Machine

1. All manufacturers, retailers, distributors, importers, dealers and technicians dealing in sale, buyback or repair of Ultrasonography/ imaging machines in Himachal Pradesh are to be registered with State Appropriate Authority, PC & PNDT, and Government of Himachal Pradesh. No person will be permitted to sale/ purchase/ buy back/repair or carry out any transaction of USG imaging machine /probes or any instrument capable of detection of sex of foetus except from the dealers/ manufactures/repairers registered with State Appropriate Authority in Government of Himachal Pradesh. (As per attached application for registration).
2. Manufacturers/ dealers will sell/ buy back/repair USG machines/ imaging machine/ any other machine capable of detecting sex and probes only to those clients/ clinics which are registered with the District Appropriate Authority of the concerned district.

3. Manufacturers, retailers, distributors, importers, dealers and technicians they will report to the State Appropriate Authority, Govt of Himachal Pradesh as well as the concerted District Appropriate Authority for every transaction or repair of USG/ imaging machines prior to actual sale/buyback or repair of the machines with all the details like make, model and serial no, of the machines and probes.
4. No clinic/ doctor will purchase/ sell/ give USG machines by way of buy back or repair of any USG / Imaging machine from/ to any manufacturer, retailer distributor importer, dealer or technicians not registered with State Appropriate Authority, Govt. of Himachal Pradesh.
5. Manufacturers, retailers, distributors, importers, dealers and technicians, will keep complete record of their business at the place of their business, in serial order regarding the date, makes model & serial no. of the USG/ imaging machines/ any other machine Capable of detecting sex probes sold/ bought back/ repaired/ traded or destroyed & will submit their quarterly report of sale/ buyback to District and State Appropriate Authority within 15 days of end of every quarter, Even if the information is "Nil still it is mandatory to be reported.
6. Every manufacturer, retailers, distributor's importers, dealers and technicians will provide reasonable facilities for inspection of their record of the business to the place of their business on demand by concerned Appropriate Authority during inspection visit at all reasonable times.
7. All the transactions regarding the USG/ Imaging machines/ any other machine capable of detecting sex/ probes will be notified to the District Appropriate Authority of the concerned district by the Clinic/ Doctor as well as by concerned Manufacturers, Distributors, Retailers importers/ technician.
8. Manufacturer/ dealer will report to both the State Appropriate Authority and District Appropriate Authority for every transaction of USG machine imaging machine / any other machine capable of detecting sex/ probes prior to the actual sale of the machine
9. Manufacture/ dealer will submit the report online. Till this mechanism is developed, reporting should be made on email id dhsrshimla@gmail.com and a hard copy submitted to the State Appropriate Authority, Directorate of Health Safety & Regulation, Red Cross Building, Near Raj Bhawan, Himachal Pradesh, Shimla-2.
10. The manufacturer/Dealer/ retailer's distributors/importers/ technician while doing transaction of any equipment which is capable of detection of sex of foetus will take an affidavit on stamp paper duly signed by notary public from the purchaser that no court case is pending against him/ her in any state of India in relation to PC &PNDT Act.
11. Manufacturer/ dealer will report to State Appropriate Authority, Govt of Himachal Pradesh about the buyback of old equipments and probes from the client.
12. Manufacturer/ dealer will report to State Appropriate Authority, Govt of Himachal Pradesh about the refurbishment or cannibalization of any old equipment purchased from the client.

Application Fee


- Fees for registration of all manufacturers, distributors, retailers, importers etc. shall be for importers & manufacturer – Rs 75000 (Seventy five Thousand rupees Only) and for distributor, dealer & retailer etc. – Rs 50000 (Fifty Thousand Rupees Only) for 5 Years respectively. The fees shall be utilize for effective implementation of PC & PNDT act including awareness programmes.
- Application fee once paid will not be refunded, if an application for registration has been rejected by the State Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection.
- The application fee shall be paid by a demand draft drawn in favour of the State Appropriate Authority concerned. The fees collected by the Appropriate Authorities for registration of manufacturer, retailers, distributor's importers, dealers shall be deposited by the Appropriate Authority concerned in a bank account opened in the name of the official designation of the Appropriate Authority concerned and shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the PC & PNDT Act as per Rule 5 (1 & 2).

Validity of Registration

- Every certificate of registration shall be valid for a period of ~~two~~^{five} years from the date of its issue.

All Manufacturers, Distributors, Retailers importers, technicians of Ultrasonography Imaging machines/probes any other equipment capable of detecting sex of foetus are to follow the above mentioned instructions strictly, in a bid to stop legal transactions of Ultrasonography/ imaging machines/probes or any other equipment capable of detecting sex. Any non-compliance of these instructions will be viewed as contravention of Sec 3 (B) of The PC& PNDT Act 1994 & Rule 3-A of the PC& PNDT Rules 1996 & will be liable to prosecution by the concerned Appropriate Authority.

The application form for registration is annexed as per Annexure-I, declaration form is annexed as per Annexure-II and registration certificate is annexed as per Annexure-III format are Annexed for approval please.


Chairperson
State Appropriate Authority,
PC & PNDT Act, Directorate of Health Safety
& Regulation Govt. of Himachal Pradesh

Form of Application for registration of manufacturer/supplier of ultrasound units to be made to the Appropriate Authority under PC & PNDT Act, Himachal Pradesh.

1.	Name of Company And Address																	
	Pincode																	
	Telephone No																	
	Fax No																	
	E-mail address																	
2.	Registered Office																	
	Pincode																	
	Telephone																	
	Fax No																	
	E-mail address																	
3.	Type of Organization Proprietary/Partnership/Pvt. Ltd./ Public LTD./ Other																	
4.	Type of Business in Ultrasound Business																	
	Manufacturer																	
	Importer																	
	Distributor																	
	Refurbisher																	
5.	Model Sold in India / State with specification (2D/3D/4D) any other	<p>Name of Models of Ultrasound Unit:</p> <table border="1"> <thead> <tr> <th></th> <th>Current</th> <th></th> <th>Old Models</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td>1</td> <td></td> </tr> <tr> <td>2</td> <td></td> <td>2</td> <td></td> </tr> <tr> <td>3</td> <td></td> <td>3</td> <td></td> </tr> </tbody> </table>		Current		Old Models	1		1		2		2		3		3	
	Current		Old Models															
1		1																
2		2																
3		3																
6.	Probes Sold in India/State	<p>Name of Probes supplied by the company for usage with Ultra Sound Unit:</p> <table border="1"> <thead> <tr> <th></th> <th>Current</th> <th></th> <th>Old Models</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td>1</td> <td></td> </tr> <tr> <td>2</td> <td></td> <td>2</td> <td></td> </tr> <tr> <td>3</td> <td></td> <td>3</td> <td></td> </tr> </tbody> </table>		Current		Old Models	1		1		2		2		3		3	
	Current		Old Models															
1		1																
2		2																
3		3																

7.	Details of Authorized Signatory	
8.	Name: Signature : Seal: Place: Date:	

**FORM OF APPLICATION FOR REGISTRATION OF MANUFACTURER / RETAILER/
DISTRIBUTOR / IMPORTER / DEALER / TECHNICIAN DEALING IN ULTRASOUND/
IMAGING MACHINES IN HIMACHAL PRADESH**

- 1 Name of the applicant
- 2 Residential Address of the applicant:
- 3 Type of facility to be registered:

(Please specify whether the application is
For registration of a manufacturer, retailer,
distributor, importer, dealer or technician
of Ultrasound / Imaging Machine or any
combination of these)
- 4 Full name and address/addresses of
office / factory of manufacturer, retailer,
distributor, dealer importer or technician
of Ultrasound / Imaging Machine with
Telephone/ Fax number(s) / Telegraphic/
Telex/ E-mail address(es). :
- 5 Type of Ownership of Organization
(individual ownership/partnership/
Company/ co-operative/ any other to be
specified). In case type of organization is
other than individual ownership, furnish
copy of articles of association and names
and addresses of other persons responsible
for management, as enclosure.
- 6 Specification of the product/ Merchandise
Service & probes for which approval is sought:-
- 7 Equipments/ services available with the
Make and model of each equipment or
Type of repair work under taken.
- 8 Names, qualifications, experience of
Employees (may be furnished as an
Enclosure

9 List of Enclosures:

(Please attach a list of relevant enclosures/
Supporting documents attached to this
application viz.

- (1) Electricity bill/ Telephone bill/ Tax bill
For address proof of residence/ Office.)
- (2) Photo Identify- PAN Card/ Passport/
ADHAR/ Voter ID or Election
Commission card/ Driving Licence.
- (3) Partnership Deed/ Registration of
Company/Firm Registration Documents.
- (4) Authorized Dealership certificate/
Documents of Retailership or any other
documents pertaining to their business.
Attach the documents which are applicable.

Date:

Place

(.....)

**Name, designation and signature of the person
Authorized to sign on behalf of the organization
to be registered.**

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DECLARATION

I, Sh./Smt./ Kum./ Dr.....Son/daughter/wife of.....
aged.....Years, resident of.....
.....

.....Working as (indicate designation).....
..... (indicate name of the organization / Firm or
repairing station to be registered) hereby declare that I have read and understood the Pre-natal Diagnostic
Techniques (Prohibition of Sex Selection) Act, (57 of 1994) and the Pre-natal Diagnostic Techniques
(prohibition of Sex Selection) Rules, 1996.

It is further declared that no case is pending / Sub-judice any court under PC & PNDDT Act.

I also undertake to explain the said Act and Rules to all employees of the organization / Firm or
repairing station in respect of which registration is sought and to ensure that Act and Rules are fully
complied with.

I affirm that all information given in this application are true & correct.

Date: (.....)

Place: **Name, designation and signature of the person
Authorized to sign on behalf of the organization
to be registered.**

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

Quarterly report format of Ultra Sonography/ Image Scanning Machines sold/ Repaired in the State of Himachal Pradesh

Name of the Manufacturer/ Dealer/ importer/ Distributor/ Technician:-
Registration No.

Full Address

With STD CODE-landline No.

Email id

Mobile No. of responsible person:-

Sr. No.	Name of District	Service provided /Buyback/Repair(p lease specify)	Name of Registered center with Address, Telephone No. & E-Mail id	Name of owner with Address, Telephone No. & Email id	Name of equipment Ultrasound/Machine -2D/3D/4D/imaging Machine/ Other equipment (please specify)	Make/model & serial no. of the equipment to be purchased/repaird including portable Machines with year of manufacture.	Date of expected sale/delivery/ repair of the USG/Imagin g machine	PC & PNDT Registration No. with date, date of expiry of validity & detail of issuing Authority.	Remarks, if any

To be submitted in hard as well as soft copy.

To

(1) The State Appropriate Authority, PC & PNDT,
Directorate of Health Safety & Regulation Govt. of Himachal Pradesh

(2) District Appropriate Authority, PC& PNDT Act

Authorized Signatory
(Full Name & Contact no.)