

... TECHNICAL DATA SHEET ...

STERILE DISPOSABLE SET FOR PAP-SMEAR

CODE	IDENTIFICATION NO.	C.N.D. CODE	GMDN CODE
01XX	21841/R	U0899	37468

XX: indicates the content of the set that can consist of:
vaginal speculum, wooden Ayre spatula, mini container, cotton swab, examination glove, microscope slide, conic hystrometer, brush for endocervical sampling, cytological fixative in sachet and tissue. Below are described the most frequent combinations. For every variation is given a code that uniquely identifies the set.

Code examples and various compositions:

CODE	DESCRIPTION AND COMPOSITION
0161	Disposable sterile set for pap-smear consisting of: Speculum large, 1 glove, 1 mini container, 1 Ayre spatula and 1 cotton swab. Carton of 100 pcs.
0162	Disposable sterile set for pap-smear consisting of : Speculum small, 1 glove, 1 mini container, 1 Ayre spatula and 1 cotton swab. Carton of 100 pcs.
0163	Disposable sterile set for pap-smear consisting of : Speculum medium, 1 Ayre spatula and 1 cotton swab. Carton of 100 pcs.
0171	Disposable sterile set for pap-smear consisting of : 1 Speculum large, n. 1 Ayre spatula, 1 brush for endocervical sampling and 1 microscope slide. Carton of 100 pcs.
0172	Disposable sterile set for pap-smear consisting of: 1 Speculum small, 1 Ayre spatula, 1 brush for endocervical sampling and 1 microscope slide. Carton of 100 pcs.
0173	Disposable sterile set for pap-smear consisting of : 1 Speculum medium, 1 Ayre spatula, 1 brush for endocervical sampling and 1 microscope slide. Carton of 100 pcs.
0175	Disposable sterile set for pap-smear consisting of : Speculum medium , 1 mini container , 1 microscope slide, 1 Ayre spatula and 1 brush for endocervical sampling . Carton of 100 pcs.
0181	Disposable sterile set for pap-smear consisting of : Speculum large with central pin adjustment , 1 brush for endocervical sampling, 1 mini container with 2 microscope slides, 1 Ayre spatula and 1 cotton swab. Carton of 100 pcs.
0182	Disposable sterile set for pap-smear consisting of : Speculum small with central pin adjustment , 1 brush for endocervical sampling, 1 mini container with 2 microscope slides, 1 Ayre spatula and 1 cotton swab. Carton of 100 pcs.
0183	Disposable sterile set for pap-smear consisting of : Speculum medium with central pin adjustment , 1 brush for endocervical sampling, 1 mini container with 2 microscope slides, 1 Ayre spatula and 1 cotton swab. Carton of 100 pcs.
0185	Disposable sterile set for pap-smear consisting of : 1 microscope slide, 1 mini container , 1 examination glove, 1 brush for endocervical sampling and 1 Ayre spatula. Carton of 100 pcs.
0191	Disposable sterile set for pap-smear consisting of : Speculum large with side screw adjustment, 1 examination glove, 1 mini container, 2 microscope slides, 1 Ayre spatula, 1 cotton swab and 1 endometrial sampling probe, endocyte type. Carton of 50 pcs.
0192	Disposable sterile set for pap-smear consisting of : Speculum small with side screw adjustment , 1 examination glove, 1 mini container, 2 microscope slides, 1 Ayre spatula, 1 cotton swab and 1 endometrial sampling probe, endocyte type. Carton of 50 pcs.
0193	Disposable sterile set for pap-smear consisting of : Speculum medium with side screw adjustment, 1 examination glove, 1 mini container, 2 microscope slides, 1 Ayre spatula, 1 cotton swab and 1 endometrial sampling probe, endocyte type. Carton of 50 pcs.
0195	Disposable sterile set for pap-smear consisting of : Speculum medium with central pin adjustment, 2 examination gloves, 1 mini container with 2 microscope slides, 1 Ayre spatula and 1 brush for endocervical sampling. Carton of 100 pcs.
0196	Disposable sterile set for pap-smear consisting of : 2 exploration gloves, 1 mini container with 2 microscope slides, 1 Ayre spatula and 1 brush for endocervical sampling. Carton of 100 pcs.
0199	Disposable sterile set for pap-smear consisting of : 2 exploration gloves, 1 mini container with 2 microscope slides, 1 Ayre spatula, 1 brush for endocervical sampling, 1 sachet cytological fixative and 1 tissue. Carton of 100 pcs.

TRADE MARK	HOSPITAL' S KIT
MANUFACTURER	G.P.S. S.R.L. – Via Del Chioso n. 8 – 24030 Mozzo (BG) Tel. 035-4376456 Fax 035-617844 E-mail: gps@gpsmedical.com website: www.gpsmedical.com
CLASS	I STERILE
REFERENCE	Products conforming to directive 93/42/CEE dd 14.06.1993, ANNEX IX, Regola 5
CE MARKING	 certificate n° 099 QPS 301 09, issued the 22.05.09 Of Notified Body 0373 Istituto Superiore di Sanità– Roma

1. USE

The Pap Test is a painless test to detect the presence of abnormal cells in the cervix. It allows early detection of cervical cancer.

The functional configuration of the kit allows immediate use.

The kit can contain the following product types:

- n. 1 speculum with side screw or central pin adjustment in various sizes.
- n. 1 wooden Ayre spatula.
- n. 1 cotton swab.
- n. 1 brush for endocervical sampling.
- n. 1 or 2 microscope slides.
- n. 1 or 2 examination gloves.
- n. 1 mini container for microscope slides.
- n. 1 endometrial sampling probe.
- n. 1 sachet fixative.
- n. 1 tissue

2. INSTRUCTIONS

1. Put on examination glove.
2. Insert the speculum with closed valves into the vaginal cavity. Gently bring together the two handles to open the valves and dilate the cavity . Turn the screw on the pin so that the handles are locked.
3. Proceed with the removal of cells from the esocervix, transformation zone and posterior fornix, using the wooden Ayre spatula.
4. Put the removed cells on a first slide and fix with fixative, cytologic spray (our code 0139).
5. Complete the pap-test by taking samples with the cotton swab and the endometrial sampling probe.
6. Put the samples with gentle pressure on the second slide; fix also the second sample with fixative, cytologic spray (our code 0139).
7. Put both of the slides with the samples in the plastic container (mini container).

3. FEATURES

- **PHTALATES** : The raw material of the product is phtalate-free.
- **LATEX FREE**: The production material as well as the packaging material are **Latex-free.**

4. PACKAGING

The product is packed individually with a combination of heat sealed transparent cellophane (nylon/polyethylene) with white glazed medical Kraft paper. This packaging provides an adequate waterproof protection and makes sure that the product arrives at the final consumer in safe hygienic conditions. It comes in single pouches and sterilized with ethylene oxide. Carton of 50 pieces or of 100 pieces.

5. STERILIZATION/VALIDITY

Sterilization in autoclave by ethylene oxide according to the validated cycle.
Sterility is guaranteed in unopened, undamaged package - Validity: 5 years

6. PRESERVATION/STORAGE

Store in a dry place. Do not expose to direct sun light or heat sources.

7. WARNINGS

- Device to be used for gynaecological examinations only.
- Do not insist on inserting the device or even trying to open the uterus, as the speculum may break.
- The device is supplied sterile.
- The device is disposable, therefore do not re-use it again.
- Do not use if the package doesn't look intact.
- Use immediately after opening the package.

The device must be used by physicians or trained staff only.

8. ELIMINATION

The product is disposable, therefore do not re-use it. It can be discharged or burned along with other waste, in accordance with the regulations of the local authorities. The burning does not cause any toxic residues.

9. PACKAGE PRINTING

Paper printing details :

Details about paper	Weight	Colours of Print
Kraft paper white one-side glossy medical	GR. 60/sqmt.	One-colour print

- The following details are printed on the package:
 - Product description;
 - Manufacturers name;
 - Item number;
 - Sterilization date;
 - LOT number;
 - Validity;
 - Directions for use.