

CERTIFICATE

No. 490188



This is to certify that the Quality Management System of Medical Devices of

Primax Berlin GmbH

Meeraner Strasse 17e
12681 Berlin
Germany

has been assessed and found to be in compliance with the standard

ISO 13485:2016

applicable to

1) Manufacturing and Distribution of the following PRIMAX Medical Products:

- X-ray film intensifying screens
- X-ray film cassettes
- Ultrasound gel
- Electrode contact gel / spray / cream
- Dental cotton
- X-ray protective clothing

2) Distribution of the following PRIMAX Medical Products:

- Medical and Dental X-ray films

3) Distribution of Medical Merchandise for

- X-ray and Ultrasound Diagnostics
- Radiation Protection
- Medical Disinfection

The certificate has been issued under No. **490188** for the registration period from 21st June 2018 to 6th July 2020.

A handwritten signature in blue ink, likely belonging to the approving authority.

Approved by

Printed by



validity code: **C39316DD-921**

Check the validity of this certificate using this code at www.ll-c.info

LL-C (Certification) Czech Republic s.r.o. | Pobežnf 620/3, 186 00 Praha 8

www.ll-c.net



PRIMAX[®] Roll Dev

X-ray Film Developer for Roller Machines (liquid)



Description:

- X-ray Film developer for Automatic Processing in processors of roller transport type
- good sensitometric results with low fog values in a wide range of temperatures
- Because of the special oxidation stability the developer is especially suitable for machines with low and/ or irregular utilization.
- liquid concentrates, three parts (5,0 l / 2 x 0,5 l)

Replenishment:

- For processing of 1 m² X-ray film **400 to 600 ml** replenisher are necessary at standard conditions.
- Generally replenishment occurs automatically by addition of the solution depending on film amount.

Mix Instructions:

Water	Part A	Part B	Part C	Water
10,0 l	5,0 l	0,5 l	0,5 l	4,0 l

- First dissolve part A completely in water, afterwards add part B under permanent stirring and then part C in the same way.
- Finally add water to get 20 l ready-to-use product.

Mixing of X-ray developer working solution:

To prepare a fresh working tank solution, add 25 mls of Starter concentrate per Litre of tank volume to the ready mixed replenisher.

Assortment:

Order Number	Product Name	Mix Size for	Contents per unit (concentrates)	Capacity for ... m ² film
209500	Primax Roll Dev	2 x 20 l	Part A 2 x 5,00 l Part B 2 x 0,50 l Part C 2 x 0,50 l	65-100

PRIMAX[®] Roll Fix

X-ray Film Fixer for Roller Machines (liquid)



Description:

- X-ray Film fixer for Automatic Processing in processors of roller transport type with fixing times at 15 s or more
- Because of its excellent hardening properties and fast working fixer components this product is suitable for use in fast going machines.
- for medium to high production volume
- application in conjunction with Developer Primax Roll Dev
- liquid concentrates, two parts (5,0 l / 1,25 l)

Replenishment:

- For fixing of 1 m² X-ray film **600 to 800 ml** replenisher are necessary at standard conditions.
- Generally replenishment occurs automatically by adding solution depending on film amount.

Mix Instructions:

Water	Part A	Part B	Water
10,0 l	5,0 l	1,25 l	3,75 l

- First dissolve part A completely in water, afterwards add part B under permanent stirring.
- Finally add water to get 20 l ready-to-use product.

Assortment:

Order Number	Product Name	Mix Size for	Contents per unit (concentrates)	Capacity for ... m ² film
209505	Primax Roll Fix	2 x 20 l	Part A 2 x 5,0 l Part B 2 x 1,25 l	50-65

Storage and Handling of Roll Dev and Roll Fix:

- These chemicals are suited for all kinds of processors, except of tabletop processors, and for all processing cycles.
- Make sure the processing room is well ventilated. Air ventilation of 10 times the room volume per hour is recommended.
- Until the preparation the concentrates have to be kept in the closed original package and stored at temperatures of 4 to 24 °C.
- X-ray Film chemicals contain components which may cause irritations in case of contact with the skin.
- In case of contact with the eyes it has to be rinsed thoroughly with plenty of running cold water by opened eyelid and a medical doctor has to be consulted.
- The disposal of used photographic processing solutions has to be done in accordance with the legal regulations.
- Consult the Safety Data Sheet for further detailed information relating safety, health and environmental aspects.
- Easy bottle opening: Simply open the cap, place it upside down on the bottle, apply a little pressure and turn the cap clockwise to break the ECO seal
- Easy automatic mixing: You can easily mix the parts using automatic mixing units. Remove the cap, invert the bottle with the ECO seal over the seal opener and press. The seal is automatically broken and the contents can flow into the tank of the mixing unit.