

CERTIFICATE OF CONFORMITY FOR QUALITY MANAGEMENT SYSTEM

Is hereby certified that the quality management system for:
Design and development, production and distribution of silicone patch, gel for scars and cicatrices, pregnancy tests, fetal fibronectin tests, physiological underwear, gynecological pessaries and obstetric pessaries

implemented by:
"SINTETH" LLC

Legal address:
 St. 32, Enerhetykiv, Ladyzhin, Vinnytsia region, 24321, Ukraine

Production site	Activities conducted
St. Ac. Belelyubskoho, 68, office 317-324, Dnipro, Dnipropetrovsk region, 49019, Ukraine	Design and development, production and distribution of silicone patch and gel for scars and cicatrices, pregnancy tests, fetal fibronectin tests and physiological underwear



80104
 ДСТУ EN ISO/IEC 17021-1

conforms with requirements of the standard:
DSTU EN ISO 13485:2018 «Medical Devices – Quality management systems – Requirements for regulatory purposes»

Conformity of the certified quality management system with requirements of the mentioned standard shall be assessed through performance of periodic surveillance audits

Certificate No. 029-20

Valid from January 09, 2023

Valid until January 08, 2026

Version No.3. Registration date: May 19, 2023

IMPROVE MEDICAL LLC

Seat of Legal Body:
1/27, M.Pryimachenko Blvd., office 506-4, Kyiv, 01042, Ukraine

Seat of Conformity Assessment Body:
8a, Ryzka Str., office 110, Kyiv, 04112, Ukraine



Head of conformity assessment body
Svitlana Zgonnyk

HISTORY OF CERTIFICATE

No. edition	Date	Description of changes
1	January 10, 2020	First issue
2	October 27, 2022	Recertification
3	May 19, 2023	Gynecological pessaries and obstetric pessaries have been added to the scope of certification



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