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HARKE GROUP

04 | 2021



PHARMA

HARKE Pharma
HARKE GROUP Life Sciences Division



YOUR DOSAGE FORM EXPERTS



YOUR DOSAGE FORM EXPERTS



Thorsten Harke | President HARKE GROUP



HARKE Pharma

is your technology driven distributor for innovative excipients.

HARKE Pharma

stands for more than 40 years of supporting our Customers in their development and optimization of innovative dosage forms, by offering extensive technical support, rounded up by a broad range of specialized excipients and selected APIs.

By closely monitoring the ever-changing markets, we identify the latest technological and scientific trends, supporting our Customers to implement them. Our in-house experts are available to efficiently work with our Customers on projects, from concept to commercialization. Utilizing our extensive quality-driven product portfolio, we are able to offer a unique and effective partnership.



Daniel Burchart | Board Member Life Sciences Managing Director HARKE Pharma GmbH

HARKE GROUP

The mother company of HARKE Pharma is a family-owned, international group, offering speciality materials, technical support and customized solutions, including formulating, blending and contract packaging for technical applications.

HARKE GROUP Life Sciences Division

- HARKE Pharma
- HARKE Nutraceuticals
- HARKE Food
- HARKE Feed

Facts & Figures

HARKE GROUP

| FOUNDED | TURNOVER | DISTRIBUTING IN | EMPLOYEES | OFFICES |
|---------------------|------------|-----------------|----------------|--------------|
| 1965 | € 150 Mio. | 63 Countries | 220 Group-wide | 15 in Europe |
| Mülheim an der Ruhr | in 2020 | | | |

EUROPE-WIDE ASSISTANCE

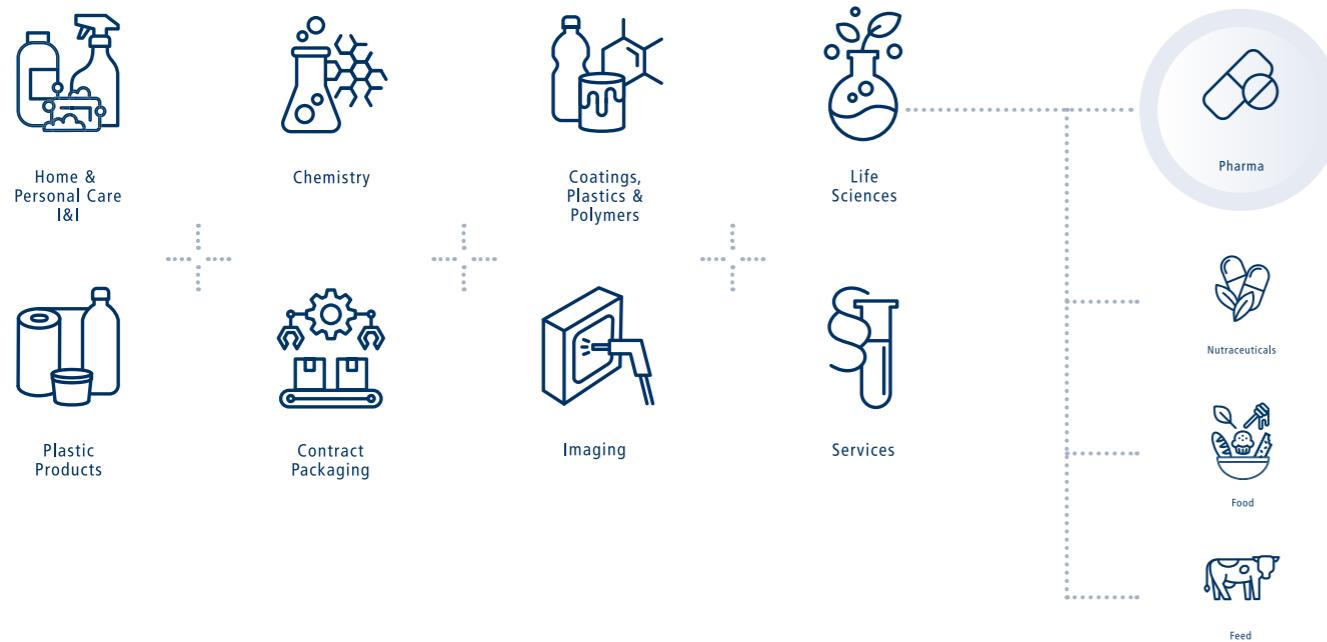
With offices across many European countries, we are able to offer our Partners a local presence. Using local languages, our experts are able to provide advice and assistance, anywhere and at any time.



HARKE PHARMA

| FOUNDED | CUSTOMER BASE | DELIVERIES | REPRESENTING | COMPLAINTS |
|---------------------|----------------------|--|-----------------------------|---------------------------|
| 1982 | 1200 in 35 countries | approx. 1500 annually with OTIF rate of 97 % | 20 producers > 300 products | < 1 % of completed orders |
| Mülheim an der Ruhr | | | | |

HARKE DIVISIONS



● Headquarters ● Subsidiaries ● Production/Storage ● Sales Offices

Our Services



Products by Application

COATING



Glatt Tablet Coater GCC 150

Coating protects the API, individualizes the tablet and can modify the release profile.

Polymers

- Acrylates
- Hypromellose, HPMC
- HPMC Acetate Succinate
- HPMC Phthalate
- Isomalt
- Methylcellulose, MC
- Polyvinyl Alcohol, PVA
- Shellac

Cores/Additives

- Macrogol
- MCC Starter Cores
- Sugar Pellets
- Tartaric Acid Cores
- Talc
- Xylitol Pellets

YOUR BENEFITS:

Various high-quality products at competitive prices for your independent coating solutions.

SUSTAINED RELEASE



The development of controlled release matrix or coating systems requires polymers in good batch to batch reproducibility.

Matrix Agents

- Acrylates
- High-viscous HPMC
- Polyethylene Oxide, PEO
- Polyvinyl Alcohol, PVA

Controlled Release Coating

- Acrylates

Dissolution Retardant

- Talc

YOUR BENEFITS:

A wide range of products suitable for various technologies for your sophisticated formulations.



TABLETTING



DC excipients and easy-to-use solutions for ODTs and mini-tablets are increasingly required by the industry to grant high production yield.

Commodities

- Crosslinked PVP
- Gelatine
- Hypromellose, HPMC
- Macrogol
- Microcrystalline Cellulose, MCC
- Polyvinylpyrrolidone, PVP
- Talc

Blends/Premixes

- GRANFILLER-D™
- HarkePlus Tab® (Prime)
- HiSORAD™
- SmartEx™

Specialities

- Hypromellose SR
- Isomalt
- Low-substituted HPC
- Methylcellulose, MC
- Sodium Chloride
- Sucrose Ester

YOUR BENEFITS:

A full basket of excipients, from commodities to problem solvers, which adds value to your formulation.

SOLUBILITY ENHANCEMENT



Many modern drugs show poor solubility and bioavailability. Solubility enhancement consequently becomes more important.

Carriers for Solid Dispersion

- Acrylates
- Hypromellose, HPMC
- HPMC Acetate Succinate
- HPMC Phthalate
- Macrogol
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

Specialties

- Isomalt
- Sucrose Ester
- Tartaric Acid Cores

YOUR BENEFITS:

Solutions dedicated to tackle solubility problems backed up with state-of-the-art supportive data.

Products by Application

GRANULATION



In various cases different types of granulation are needed to improve technological properties of the powder.

Binder

- Gelatine
- Hypromellose, HPMC
- Methylcellulose, MC
- Microcrystalline Cellulose, MCC
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

Binder/Disintegrant

- Isomalt
- Low-substituted HPC

YOUR BENEFITS:

Various excipients and grades, to suit either wet or dry granulation processing.

PELLETIZATION



Pellets are produced by e.g. direct pelletization, extrusion-spheronization or using neutral starter cores for layering.

Extrusion – Spheronization

- Hypromellose, HPMC
- Isomalt
- Low-substituted HPC
- Microcrystalline Cellulose, MCC
- Polyvinyl Alcohol, PVA
- Polyvinylpyrrolidone, PVP

Layering

- MCC Starter Cores
- Sugar Pellets
- Tartaric Acid Cores
- Xylitol Pellets

YOUR BENEFITS:

Time and cost savings, during the production process, increasing production yield.

PATCH SYSTEMS



The demand for topical finished dosage forms is increasing and the use of patch systems is rising continuously.

Preservatives/Antiseptics

- Chlorhexidine Salts

Sticking Agent

- Polyvinyl Alcohol, PVA

YOUR BENEFITS:

Innovative ingredients in different grades at competitive prices.

OPHTHALMICS



Applications for ophthalmic treatment require raw materials with a good bioavailability and microbiological purity.

pH Modifiers

- Potassium Hydroxide Pellets
- Sodium Hydroxide Pellets

Thickeners/Vehicles

- Macrogol
- Methylcellulose, MC
- Polyvinyl Alcohol, PVA

Tonicity Agents

- Sodium Chloride

YOUR BENEFITS:

High-quality material at competitive prices with outstanding technical back-up.



Products by Application

SEMI-SOLIDS & LIQUIDS



Semi-solid and liquid dosage forms can be produced in shorter times and higher batch output.

pH Modifiers

- Potassium Hydroxide Pellets
- Sodium Hydroxide Pellets

Thickeners & Gelling Agents

- Hypromellose, HPMC
- Microcrystalline Cellulose, MCC

Surfactants

- Polyvinyl Alcohol, PVA
- Sucrose Ester

Sweetener

- Isomalt

Others

- Chlorhexidine Salts
- Macrogol
- Sodium Chloride
- Talc

YOUR BENEFITS:

A tailored choice of specialities.

CAPSULES



Innovative capsule locking systems, prevent additional processing, e.g. no banding for semi-solid encapsulation required.

Empty Hard Capsules

- HPMC, Gelatine and Pullulan
- BSE & TSE free
- 9 sizes in 2000 colors
- Three different locking systems

Layering

- GELITA® Gelatine (pig/bovine, Type A/Type B)
- GELITA® EC
- GELITA® RXL
- GELITA® RXL R²

YOUR BENEFITS:

Competitive capsules to serve individual needs, delivered in even small volumes, within a short time frame.

CLEAN BOTTLES AND CONTAINERS



Primary packaging for high-purity reagents, solvents and any other liquid formulation with the need for highest cleanliness levels.

Sophisticated Quality

- Manufactured under Clean Room conditions, using specially selected, high-purity PE resin
- Minimum particle counts, extractables and leachables
- Light weight, yet strong physical properties, leakage-proof
- Quality documented by COA

Characteristics

- Monolayer and multilayer bottles
- Wide and narrow mouth size
- Optional UV-light protection, solvent barrier layer, low residue construction
- From 100 ml up to 22.5 Liter, equally 200 Liter drums

YOUR BENEFITS:

High purity, no pre-cleaning, flexible quantities.

HYPERCLEAN™ PE-FILM/FINE BAG



High-level primary packaging with Aicello HYPERCLEAN™ PE-Film and antistatic FINE BAG for pharmaceutical use.

Sophisticated Quality

- Compliance to EP, USP and JP; DMF (FDA) available
- Processed in Clean Room Environment from carefully selected PE-resin
- Minimum particles, extractables and leachables
- Physical strength, low outgassing

Characteristics

- Long-lasting antistatic properties (optional)
- UV-light shield (optional)
- Various bag sizes and forms or tube roll available

YOUR BENEFITS:

Premium-quality primary packaging for sensitive APIs and intermediates, mostly available in flexible quantities.

Typical Applications

| TRADE NAME | COMMON NAME | Instant Release Coating | Modified Release Coating | Protective Coating | Taste Masking | Filler/Diluent | Dry Binder (DC+RC) | Binder Solutions (WG) | Disintegrant | Lubrication/Glidant | Anti-Capping | Modified Release (DC+WG) | Drug Layering | Extrusion-Spheronization | ODT | ODF | Stabilizing agent | Dissolution enhancer | Mini-Tablets | SD solvent free method | SD solvent method | pH Modification | Thickener | Emulsifier | Eye Drops | Mucoadhesive agent | TDS/Penetration | Capsule shell | Dispersing Aid (capsules) | ENCAPSULATION |
|----------------------|------------------------|-------------------------|--------------------------|--------------------|---------------|----------------|--------------------|-----------------------|--------------|---------------------|--------------|--------------------------|---------------|--------------------------|-----|-----|-------------------|----------------------|--------------|------------------------|-------------------|-----------------|-----------|------------|-----------|--------------------|-----------------|---------------|---------------------------|---------------|
| Cellets® | MCC Pellets | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DRUGCOAT® | Acrylates | ● | ● | ● | ● | | | | | | | | ● | | | | | | | ● | ● | | | | | ● | | | | |
| Eka Pellets™ | NaOH/KOH | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| galenIQ™ | Isomalt | ● | | | ● | ● | ● | ● | | | | | | | | | | | ● | ● | ● | | | | | | | ● | | |
| GELITA® | Gelatine | | | | ● | | | | | | | | | | | | | | | | | | | | | | | ● | | |
| GOHSENOL™ EG | PVA | ● | | ● | ● | | | | | | | | | | | | | | ● | ● | ● | | | | | | ● | | | |
| GRANFILLER-D™ | Premix | | | | | ● | | | ● | | | | | | | | | | ● | | ● | | | | | | | | | |
| HarkePlus® Tab | Premix | | | | | ● | ● | ● | ● | | | | | | | | | | | | | | | | | | | | | |
| HiSORAD™ | Premix | | | | | ● | | | ● | | | | | | | | | | ● | | ● | | | | | | | | | |
| HPMCP HP | HPMC Phthalate | ● | | | ● | | | | | | | | | | | | | | ● | ● | ● | | | | | | | | | |
| L-HPC | Low-substituted HPC | | | | | | ● | | ● | ● | | | | | | | | | ● | ● | ● | | | | | | | ● | | |
| METOLOSE® SH/SR | HPMC | | | | | | | | | | | | | | | | | | ● | ● | ● | | | | | | ● | ● | ● | |
| METOLOSE® SM | MC | ● | | | ● | | | | | | | | | | | | | | ● | | | | | | | | ● | | ● | |
| PEO-NF | PEO | | | | | | ● | | ● | | | | | | | | | ● | | | | | | | | | ● | ● | | |
| PHARMACOAT® | HPMC | ● | | ● | ● | ● | ● | ● | ● | | | | | | | | | | ● | ● | ● | | | | | | | ● | | |
| pharm-a-spheres® | Sugar Pellets | | | | | | | | | | | | | | | | | | ● | | | | | | | | | | | |
| Polyglykol | PEG/Macrogol | ● | | | | | | | | | | | | | | | | | ● | | | | | | | | | | ● | |
| Primecel® | MCC | | ● | | | | | | | | | | | | | | | ● | | | | | | | | | | | | |
| PVP K | PVP | ● | | ● | | | | | | | | | | | | | | ● | ● | ● | | | | | | | ● | | ● | |
| PVP VA 64 | Copovidone | ● | | ● | | | | | | | | | | | | | | ● | ● | ● | | | | | | | | | ● | |
| PVPP XL/CL | PVP, crosslinked | | | | | | | | | ● | | | | | | | | ● | | | | | | | | | | | | |
| SANAL® P | Sodium Chloride | | | | | | | ● | | | | | | | | | | | | | | | | | | | | ● | | |
| Shin-Etsu AQOAT® | HPMC Acetate Succinate | | ● | | ● | | | | ● | | | | | | | | | ● | | | | | | | | | | | | |
| SmartEx™ | Premix | | | | | | | | | ● | | | | | | | | ● | | | | | | | | | | | | |
| SSB® Pharma/AQUAGOLD | Shellac | | ● | | ● | ● | ● | ● | | | | | | | | | | | ● | | | | | | | | | | | |
| SURFHOPE® SE | Sucrose Ester | | | | | | | | | | ● | | | | | | | ● | | | | | | | | | | ● | ● | ● |
| Talc | Talc | ● | ● | ● | ● | ● | ● | ● | | | | | | | | | ● | | | | | | | | | | | | ● | |
| TAP® | Tartaric Acid Pellets | | | | | | | | | | | | | | | | | ● | | | | | | | | | | | | |

Product Categories



| ACRYLATES | CELLULOSE DERIVATIVES | POLYETHYLENE OXIDE |
|------------------------------------|--------------------------------|--------------------------------------|
| DRUGCOAT® E | HPMC-P | PEO-NF |
| DRUGCOAT® FS | Hydroxypropyl Methylcellulose | |
| DRUGCOAT® L | Hypromellose | POLYVINYL ALCOHOL |
| DRUGCOAT® NE | Hypromellose Acetate Succinate | GOHSENOL™ EG |
| DRUGCOAT® RL | Hypromellose Phthalate | |
| DRUGCOAT® RS | L-HPC | POLYVINYL PYRROLIDONE |
| DRUGCOAT® S | Low-substituted HPC | Copovidone |
| Methacrylic Acid Copolymers | Methylcellulose | Crospovidone |
| ACTIVES/DISINFECTANTS | METOLOSE® SH | Crosslinked PVP |
| Chlorhexidine | METOLOSE® SM | Povidone |
| Chlorhexidine Diacetate | PHARMACOAT® | |
| Chlorhexidine Digluconate, 20 % | Shin-Etsu AQOAT® (HPMC-AS) | PRIMARY PACKAGING |
| Chlorhexidine Dihydrochloride | TYLOPUR® | |
| ALKALI | GELATINE | Aicello Clean Bottles and Containers |
| Eka Pellets™ | GELITA® EC | Aicello FINE BAG |
| Potassium Hydroxide Pellets | GELITA® Gelatine | Aicello HYPERCLEAN™ PE-film |
| Sodium Hydroxide Pellets | GELITA® RXL | |
| | GELITA® RXL R ² | SALTS |
| ISOMALT | | SANAL® P |
| | galenIQ™ | Sodium Chloride |
| BLENDs/PREMIxES | MACROGOL | SHELLAC |
| GRANFILLER-D™ | PEG | AQUAGOLD (Aqueous Shellac Solution) |
| HarkePlus Tab® (Tabletting Premix) | Polyethylene Glycol (PEG) | Bleached Shellac |
| HarkePlus Tab® Prime | Polyglykol | SSB® AQUAGOLD |
| HiSORAD™ | | SSB® Pharma |
| SmartEx™ | | |
| CAPSULES | PELLETS | SUCROSE ESTER |
| Gelatine | Cellets® (MCC Spheres) | Sucrose Behenate |
| HPMC | Ibuprofen DC 100 | Sucrose Laurate |
| Pullulan | Ibuprofen Pellets | Sucrose Oleate |
| SUNLOC | Neutral Pellets | Sucrose Palmitate |
| | Sugar Pellets | Sucrose Stearate |
| | TAP® Pellets | SURFHOPE® SE |
| CELLULOSE | | TALC |
| Chemcel™ | Tartaric Acid Pellets | Micro ACE |
| Microcrystalline Cellulose | Xylitol Pellets | Talc MS |
| Primecel™ | | Rose Talc |

Products A-Z



| A | G | P |
|--------------------------------------|------------------------------------|------------------------------|
| Acrylates | GELITA® RXL R ² | PHARMACOAT® |
| Aicello Clean Bottles and Containers | GOHSENOL™ EG | Polyethylene Glycol (PEG) |
| Aicello FINE BAG | GRANFILLER-D™ | Polyethylene Oxide (PEO) |
| Aicello HYPERCLEANTM PE-film | | Polyglykol |
| AQUAGOLD (Aqueous Shellac Solution) | | Polyvinyl Alcohol (PVA) |
| B | H | |
| Bleached Shellac | HarkePlus Tab® (Tabletting Premix) | Polyvinylpyrrolidone (PVP) |
| | HarkePlus Tab® Prime | Potassium Hydroxide Pellets |
| | HiSORAD™ | Povidone |
| | HPMC-P | Primecel™ |
| C | | R |
| Capsules (Gelatine, HPMC, Pullulan) | Hydroxypropyl Methylcellulose | |
| Cellets® (MCC Spheres) | Hypromellose | Rose Talc |
| ChemiceI™ | Hypromellose Acetate Succinate | |
| Chlorhexidine | Hypromellose Phthalate | |
| Chlorhexidine Diacetate | I | S |
| Chlorhexidine Digluconate, 20 % | Ibuprofen DC 100 | SANAL® P |
| Chlorhexidine Dihydrochloride | Ibuprofen Pellets | Shellac |
| Copovidone | Isomalt | Shin-Etsu AQOAT® (HPMC-AS) |
| Crospovidone | Crosslinked PVP | SmartEx™ |
| | L | Sodium Chloride |
| | L-HPC | Sodium Hydroxide Pellets |
| | Low-substituted HPC | SSB® AQUAGOLD |
| D | | SSB® Pharma |
| DRUGCOAT® E | | Sucrose Behenate |
| DRUGCOAT® FS | | Sucrose Laurate |
| DRUGCOAT® L | Macrogol | Sucrose Oleate |
| DRUGCOAT® NE | Methacrylic Acid Copolymers | Sucrose Palmitate |
| DRUGCOAT® RL | Methylcellulose | Sucrose Stearate |
| DRUGCOAT® RS | METOLOSE® SH | Sugar Free Pellets (Xylitol) |
| DRUGCOAT® S | METOLOSE® SM | Sugar Pellets |
| | Micro ACE | SUNLOC |
| | Microcrystalline Cellulose | SURFHOPE® SE |
| E | | T |
| Eka Pellets™ | | Talc |
| G | N | Talc MS |
| galenIQ™ | Neutral Pellets | |
| Gelatine | P | TAP® Pellets |
| GELITA® EC | PEG | Tartaric Acid Pellets |
| GELITA® Gelatine | PEO-NF | TYLOPUR® |
| GELITA® RXL | | |

Our Partners & Products

#OnePartnerOneResponsibility

We have a carefully selected raw material portfolio, primarily used for solid and semi-solid dosage forms.

Our experience of marrying the expectations of our Principals, with the needs of our Customers, means that we have a focused list of products, from hand-picked Principals, ideally suited to the possible applications of our Customers.

This helps us to offer the outstanding and well-known HARKE service level.



Japanese Clean Room manufacturing of high-purity primary PE-packaging materials (Joint-venture with HARKE: AICELLO-HARKE GmbH).

- Clean Bottles & Containers
- HYPERCLEAN™ PE-Film
- FINE BAG



Long established and major manufacturer of PVA.

- PVA



Leading supplier of various food ingredients with a niche in pharma.

- Sucrose Ester



Our sourcing agent in China.



The largest Japanese producer of superior quality Talc products.

- Talc



Beneo is part of the Südzucker group. Specialist for naturally derived functional ingredients.



Fast growing, quality-focused, family-owned cellulosics manufacturer.



Multinational company, active in various fields in the chemical industry, with a special focus on quality.



Leading producer of a diverse range of chemicals, with a special focus on innovative co-processed excipients.

- Isomalt

- MCC

- Polyglykol

- GRANFILLER-D™
- HiSORAD™



One of the leading manufacturers of pharmaceutical Povidones with a high responsibility for environmental compliance.

- KoVidone®
- PolyKoVidone®
- OraRez®



Since 1905 producer in Bohus (Sweden) for purest alkali pellets of NaOH/KOH and since 1918 for pharmaceutical salt in Mariager Fjord (Denmark).

- Highly purified NaOH, KOH
- SANAL® P, Pharmaceutical NaCl



Family-owned company previously specializing in dragées, now offering a wide range of globuli & neutral starter cores.



Leading supplier of Cellulose derivatives.

- Isomalt

- MCC

- Polyglykol

- GRANFILLER-D™
- HiSORAD™

Globally active producer of high quality Gelatine, as well as Collagen and Collagen peptides.



Our own brand, offering solutions to a range of formulation challenges.



German manufacturer, with knowledge and experience in producing highly spherical particles.



Family-owned manufacturer of high quality APIs.

- Gelatine

- Blends/Premixes
- HarkePlus Tab®
- HarkePlus Tab® Prime

- Neutral MCC Pellets
- Ibuprofen Pellets 100 %
- Tartaric Acid Pellets

- Chlorhexidine Salts



Manufacturer of outstanding quality Shellac specialities, based in Northern Germany.

- Shellac Aqueous Solution
- Shellac Flakes



Japanese manufacturer of PEO.

- PEO



Major Indian manufacturer of empty hard capsules.



EXCiPACT certified producer of Acrylate based coating polymers, located in India.

- Capsules
 - HPMC
 - Gelatine
 - Pullulan

- Methacrylic Acid Copolymers

Why HARKE

one group of **16** companies | **15** offices in Europe | **6** divisions

25 business units | **15** diverse service functions | **3** laboratories | **2** production sites

over **220** employees | working with **30** industries | in more than **63** countries | on **4** continents

with over **3,000** customers | and more than **40,000** deliveries per year

10 reasons to collaborate with HARKE

relevant portfolio | long-standing business relations | growing company group

excellent technical know-how | responsible partner | fast action | sustainable enterprise

digitization | stable management | passionate people

countless opportunities for a successful and future-oriented collaboration

